UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

COCKE COUNTY, TENNESSEE,

Plaintiff,

v.

ELI LILLY AND COMPANY; NOVO NORDISK INC.; SANOFI-AVENTIS U.S. LLC; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; CAREMARKPCS HEALTH, LLC; CAREMARK, LLC; CAREMARK RX, LLC; EVERNORTH HEALTH, INC. (F/K/A EXPRESS SCRIPTS HOLDING COMPANY); EXPRESS SCRIPTS, INC.; EXPRESS SCRIPTS ADMINISTRATORS, LLC; MEDCO HEALTH SOLUTIONS, INC.; ESI MAIL PHARMACY SERVICES, INC.; EXPRESS SCRIPTS PHARMACY, INC.; UNITEDHEALTH GROUP, INC.; OPTUM, INC.; OPTUMRX INC.; OPTUMRX HOLDINGS I LLC; OPTUMINSIGHT, INC.,

Defendants.

Civil Action No. _____

COMPLAINT

JURY TRIAL DEMANDED

Complaint and Demand for Jury Trial

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Plaintiff, Cocke County, Tennessee ("Plaintiff," the "County" or "Cocke County"), by and through undersigned counsel, brings this lawsuit against the above-named Defendants and alleges as follows:

INTRODUCTION

1. The cost of diabetes medications has risen more than tenfold over the past 20 years. Over the same period of time, the average cost of consumer goods and services has risen just 1.75-fold. The skyrocketing prices of diabetes medications are not tethered the rising cost of goods, production costs, investment in research and development, or competitive market forces. Instead, Defendants engineered these price increases via an opaque, conspiratorial kickback scheme (referred to herein as the "Insulin Pricing Scheme"), which has exponentially increased their profits at the expense of payors like Plaintiff and its plan members. The Insulin Pricing Scheme is a multibillion-dollar industry.

2. Diabetes is widespread. The total estimated cost of diabetes in the U.S. in 2017, according to the American Diabetes Association, was $327 billion. One in four healthcare dollars is spent caring for people with diabetes.

3. As of 2020, more than 13% of adults in Tennessee have been diagnosed with diabetes.[1] An additional 9.9% of the Tennessee adult population are prediabetic, with blood glucose levels higher than normal but not yet high enough to be diagnosed as diabetic.[2] In Cocke, approximately 9.5%, of adult residents are living with diabetes.[3] In Tennessee alone, diabetes costs

[1] Tennessee Diabetes Action Legislative Report, Feb. 2021, https://www.capitol.tn.gov/Archives/senate/112GA/committees/health-welfare/2021/Diabetes%20Legislative%20Report_FinalDraft.%2001-29-2021%208%2045%20pm.pdf.

[2] *Id.*

[3] United States Diabetes Surveillance System, https://gis.cdc.gov/grasp/diabetes/diabetesatlas-analysis.html# (last visited January 26, 2024).

an estimated $5.2 billion per year in direct medical costs attributed to diabetes.[4] An additional $2.1 billion is spent on indirect costs from attributed to diabetes.[5]

4. Diabetics in Tennessee generally rely on daily insulin treatments, oral medications, or a combination of both to treat and control diabetes. Defendants Eli Lilly, Novo Nordisk, and Sanofi (collectively, the "Manufacturer Defendants" or the "Manufacturers") manufacture the vast majority of insulins and other diabetic medications available in the United States. In 2020, as in the years preceding, the Manufacturer Defendants controlled 92% by volume, and 96% by revenue, of the global market for diabetes drugs.

5. Defendants CVS Caremark, Express Scripts, and OptumRx (collectively, the "PBM Defendants" or the "PBMs") are pharmacy benefit managers that work with the Manufacturer Defendants to dictate the availability and price of the at-issue drugs for most of the U.S. market.[6] The PBM Defendants are, at once, (1) the three largest pharmacy benefit managers in the United States (controlling more than 80% of the PBM market); (2) the largest pharmacies in the United States (comprising three of the top five dispensing pharmacies in the U.S.); and (3) housed within the same corporate families as three of the largest insurance companies in the United States—Aetna (CVS Health), Cigna (Express Scripts), and UnitedHealthcare (OptumRx).

6. These corporate conglomerate Defendants sit at 4th (CVS Health), 5th (UnitedHealth Group), and 12th (Cigna) on the Fortune 500 list as of year-end 2022.

[4] Tennessee Diabetes Profile, https://www.cdc.gov/diabetes/programs/stateandlocal/state-diabetes-profiles/tennessee.html (last visited January 26, 2024).

[5] *Id.*

[6] In the context of this Complaint, the "at-issue drugs" or "at-issue medications" are: Apidra, Basaglar, Humalog, Humulin N, Humulin R, Humulin R 500, Humulin 70/30, Lantus, Levemir, Novolin N, Novolin R, Novolin 70/30, Novolog, Ozempic, Soliqua, Toujeo, Tresiba, Trulicity, and Victoza.

Figure 1: Manufacturers, PBMs & PBM-Affiliated Insurers

Manufacturers	PBMs	PBM-Affiliated Insurer
Eli Lilly		
Novo Nordisk		
Sanofi		
	CVS	Aetna
	Express Scripts	Cigna
	Optum	UnitedHealthcare

7. For transactions in which the PBM Defendants control the insurer, the PBM, and the pharmacy (e.g., Aetna–Caremark–CVS Pharmacy), these middlemen capture as much as half of the money spent on each insulin prescription (up from 25% in 2014), even though they contribute nothing to the development, manufacture, innovation, or production of the drugs.

8. As part of this work, the PBM Defendants establish national formulary offerings (i.e., approved drug lists), which, among other things, set the baseline for which diabetes medications are covered and which are not covered by nearly every payor in the United States, including in Tennessee and, more specifically, Cocke County.

9. The Manufacturers and PBMs understand that the PBMs' national formularies drive drug utilization. The more accessible a drug is on the PBMs' national formularies, the more that drug will be purchased throughout the United States. Conversely, exclusion of a drug from one or more of the PBMs' formularies can render the drug virtually inaccessible for millions of covered persons.

10. Given the PBMs' market power and the crucial role their standard formularies play in the pharmaceutical pricing chain, both Defendant groups understand that the PBM Defendants wield enormous control over drug prices and purchasing behavior.

11. The unfair and deceptive conspiracy at the root of this complaint—the Insulin Pricing Scheme—was borne from this mutual understanding.

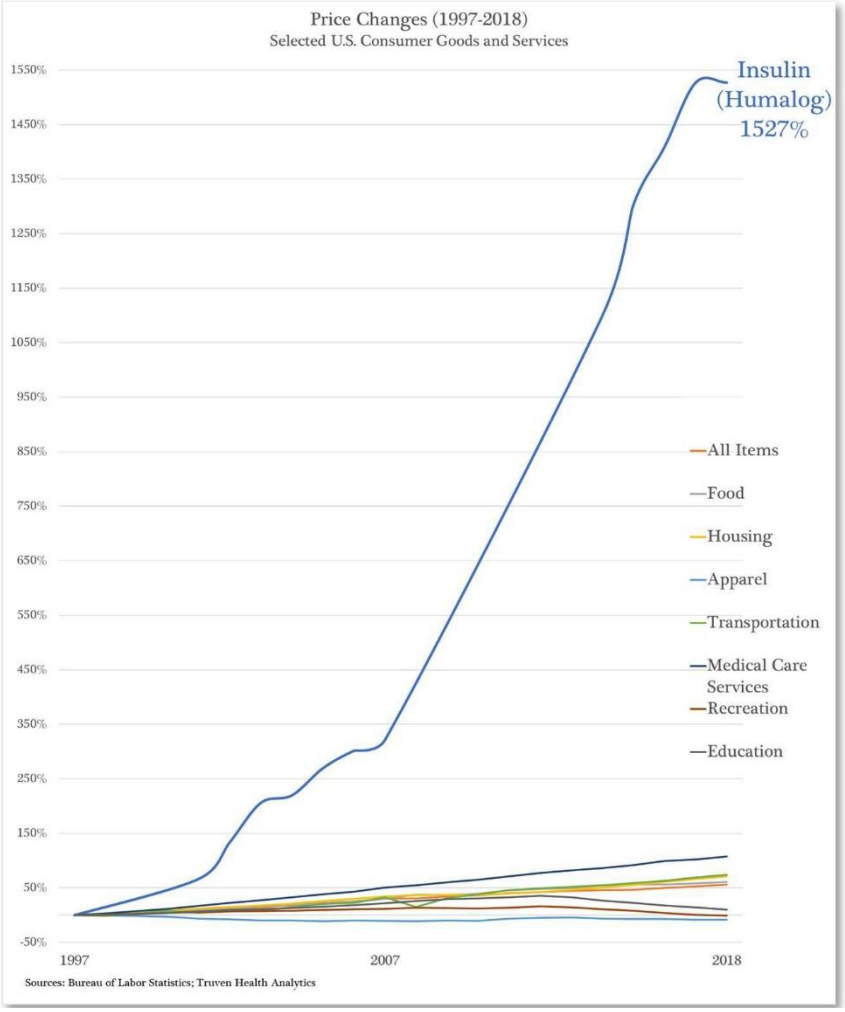
12. The Manufacturers set the initial list (wholesale) price for their respective insulin medications. Over the last 20 years, list prices have sharply increased in lockstep, even though the cost to produce these drugs decreased during that period.

13. Insulins, which today cost Manufacturers as little as $2 to produce, and which were originally priced at $20 the 1990s, now range in price from $300 to $700.

14. The Manufacturer Defendants have in tandem increased the prices of their insulins up to 1,000%, taking the same increase down to the decimal point within a few days of one another and, according to a U.S. Senate Finance Committee investigation, "sometimes mirroring" one another in "days or even hours."[7] Figure 2 shows the rate at which Defendant Eli Lilly raised the list price of its analog insulin, Humalog, compared to the rate of inflation for other consumer goods and services during the period from 1997- 2018.

[7] Charles E. Grassley & Ron Wyden, *Staff Report on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, Sen. Fin. Comm.*, at 6, 54, 55 (Jan. 2021), https://www.finance.senate.gov/imo/media/doc/GrassleyWyden%20Insulin%20Report%20 FINAL%201). Pdf (hereinafter "Grassley & Wyden" or "January 2021 Senate Insulin Report").

Figure 2: Price Increase of Insulin vs. Selected Consumer Goods, 1997-2018



15. Today's exorbitant prices do not accord with insulin's origins. The discoverers sold the original patent for $1 to ensure that the medication would remain affordable. But today, insulin is the poster child for skyrocketing pharmaceutical prices.

16. Nothing about these medications has changed over the past 100 years; today's $350 insulin is the same product Defendants once sold for $20.

How the Insulin Pricing Scheme Works

17. In the simplest terms, there are three important participants in the insulin medication chain.

a. **Cocke County.** During the relevant period, Plaintiff Cocke County operated a health plan for its employees and their dependents. The plan includes pharmacy benefits, meaning Plaintiff purchased the at-issue drugs for its beneficiaries. Operators of self-funded plans, like Plaintiff, may be referred to as payors or plan sponsors (or PBM "clients").

b. **PBMs.** Payors routinely engage pharmacy benefit managers to manage their prescription benefits, which includes negotiating prices with drug manufacturers and (ostensibly) helping payors manage drug spending. Each pharmacy benefit manager maintains a formulary—a list of covered medications. A pharmacy benefit manager's power to include or exclude a drug from its formulary theoretically should incentivize manufacturers to lower their list price. Pharmacy benefit managers also contract with pharmacies to reimburse them for medications purchased by the plan's beneficiaries. Pharmacy benefit managers are compensated by retaining a portion of what should—again in theory—be shared savings on the cost of medications.

c. **Manufacturers.** Manufacturers produce the at-issue insulin medications.[8] Each sets a list price for each of its products. The terms "list price" often is used interchangeably with the Wholesale Acquisition Cost (WAC) (defined by federal law as the undiscounted list price for a drug or biological to wholesalers or direct purchasers). The manufacturers self-report

[8] There are three types of insulin medications. First are *biologics*, which are manufactured insulins derived from living organisms. Second are *biosimilars*, which are "highly similar" copies of biologics. They are similar in concept to "generic" drugs; but in seeking approval they use biologics (rather than drugs) as comparators. Third, the confusingly-named *authorized generics* are not true generics—they are an approved brand-name drug marketed without the brand name on the label. FDA approved the original insulins as drug products rather than biologics, so although there was a regulatory pathway to introduce biosimilars generally (copies of biologics), companies could not introduce insulin biosimilars because their comparators were "drugs" rather than "biologics." In 2020, FDA moved insulin to the biologic regulatory pathway, thus opening the door to approval of biosimilars through an abbreviated approval process.

list prices to publishing compendiums such as First DataBank, Medi-Span, or Redbook, who then publish those prices.[9]

18. Given the PBMs' purchasing power and their control over formularies that govern the availability of drugs, their involvement should theoretically drive down list prices. Instead, to gain access to the PBMs' formularies, the Manufacturers artificially inflate their list prices and then pay a significant, but undisclosed, portion of the inflated price back to the PBMs (the "Manufacturer Payments").[10] The Manufacturer Payments bear a variety of dubious labels—rebates, discounts, credits, inflation/price protection fees, administrative fees, etc. By whatever name, the inflated list prices and resulting Manufacturer Payments are a quid pro quo for inclusion and favorable placement on the PBMs' formularies.[11]

19. Contracts between PBM Defendants and payors like Plaintiff tie the definition of "rebates" to patient drug utilization. But the contracts between PBMs and Manufacturers define "rebates" and other Manufacturer Payments differently—e.g., calling rebates for formulary placement "administrative fees." Defendants thus profit from the "rebates" and other Manufacturer Payments, and the payments are beyond a payor's contractual audit right to verify the accuracy of "rebate" payments they receive.

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[9] The related term Average Wholesale Price (AWP) is the published price for a drug sold by wholesalers to retailers.

[10] In this Complaint, "Manufacturer Payments" is defined as all payments or financial benefits of any kind conferred by the Manufacturer Defendants to PBM Defendants (or a subsidiary, affiliated entity, or group purchasing organization or rebate aggregator acting on a PBM's behalf), either directly via contract or indirectly via Manufacturer-controlled intermediaries. Manufacturer Payments includes rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, and any other form of consideration exchanged.

[11] Favorable or preferred placement may, for example, involve placing a branded product in a lower cost-sharing tier or relaxing utilization controls (such as prior authorization requirements or quantity limits). Favorable placement of a relatively more expensive drug encourages use of that drug and leads to higher out-of-pocket costs for payors and copayors.

20. The PBMs' staggering revenues vastly exceed the fair market value of the services they provide and, specifically, the amount of Manufacturer Payments the PBMs receive in connection with the at-issue drugs vastly exceeds the fair market value of the services they provide with respect to those drugs.

21. The Manufacturers' list prices are not the result of free-market competition for payors' business. The Manufacturers' list prices are so untethered from the net prices that the Manufacturers ultimately realize that the Manufacturers know the list price constitutes a false price. It does not reflect the Manufacturers' actual costs to produce the at-issue drugs or the fair market value of the drugs.[12]

22. The PBMs grant formulary status based upon the highest inflated price—a price that the PBMs know is false—and based upon which diabetes medications will generate the largest profits for themselves.

23. The Insulin Pricing Scheme creates a "best of both worlds" scenario for Defendants. The Manufacturer Defendants buy formulary access and increase their revenues while the PBM Defendants receive significant secret Manufacturer Payments.

24. The PBM Defendants profit off the Insulin Pricing Scheme in numerous ways, including by: (1) retaining a significant, but undisclosed, share of the Manufacturer Payments, either directly or through rebate aggregators, (2) using the price produced by the Insulin Pricing Scheme to generate unwarranted profits from pharmacies, and (3) relying on those same artificial

[12] "Net price" refers to the price the manufacturer ultimately realizes, i.e., the list price less rebates, discounts, etc. (net sales divided by volume). At times, Defendants' representatives use "net price" to refer to the amount payors or plan members pay for medications. In this Complaint, "net price" refers to the former—the amount that the Defendant Manufacturers realize for the at-issue drugs, which is roughly the List Price less Manufacturer Payments.

list prices to drive up the PBMs' margins and pharmacy related fees, including those relating to their mail-order pharmacies.

25. As detailed below, although the PBM Defendants represent both publicly and directly to their client payors that they use their market power to drive down prices for diabetes medications, these representations are false and deceptive. Instead, the PBMs intentionally incentivize the Manufacturers to inflate list prices, and the PBMs' "negotiations" intentionally drive up the price of the at-issue drugs and are directly responsible for the skyrocketing price of diabetes medications, which confers unearned benefits upon the PBMs and Manufacturers alike.

26. Because the purchase price of every at-issue diabetes medication flows from the false list price generated by Defendants' unfair and deceptive scheme, every payor in the United States that purchases these life-sustaining drugs, including Plaintiff, has been directly harmed by the Insulin Pricing Scheme.

27. Even if temporary reductions in Plaintiff's costs for the at-issue drugs occurred from time to time, those costs remained higher than the prices that would have resulted from a transparent exchange in an open and competitive market.

28. As a payor for and purchaser of the at-issue drugs, and, as a direct result of the Insulin Pricing Scheme, Cocke County has spent exorbitant amounts of capital on the at-issue diabetes medications.

29. A substantial portion of this exorbitant amount is attributable to Defendants' artificially inflated prices that did not arise from transparent or competitive market forces; rather, these inflated costs can be attributed to undisclosed dealings between the Manufacturer Defendants and the PBM Defendants as further described herein.

30. This action alleges that Defendants violated the Racketeer Influenced and Corrupt Organizations Act, Tennessee Consumer Protection Act, and Tennessee common law by engaging in the Insulin Pricing Scheme. The Insulin Pricing Scheme directly and foreseeably caused and continues to cause harm to Plaintiff.

31. This action seeks injunctive relief, restitution, disgorgement, actual damages, treble damages, punitive damages, and attorneys' fees and costs to address and abate the harm caused by the Insulin Pricing Scheme.

32. The relevant period for damages alleged in this Complaint is from 2003 through the present.

PARTIES

A. Plaintiff

33. Plaintiff Cocke County is a body corporate and politic under the laws of the State of Tennessee.

34. Plaintiff, as a government entity, provides vital services to its population of over 36,000 residents including public safety, emergency management, and health services.

35. Any increase in spending has a detrimental effect on Plaintiff's overall budget and, in turn, negatively impacts its ability to provide necessary services to the community.

36. The Insulin Pricing Scheme has had such an effect.

37. Additionally, as a government employer, Plaintiff provides health benefits to its employees, retirees, and their dependents ("Beneficiaries"). These benefits include paying for Beneficiaries' pharmaceutical drugs, including the at-issue diabetes medications. Plaintiff also purchases the at-issue diabetes medications for use in county-run facilities.

38. Plaintiff maintains a self-insured health plan for its Beneficiaries.

39. Exclusive of the costs associated with providing diabetes medications at county-run facilities, such as correctional facilities, Plaintiff spends thousands of dollars per year on the costs of providing diabetes medications for its health-plan members. Accordingly, during the relevant period, and to the detriment of its Beneficiaries and taxpayers, Plaintiff has paid millions of dollars more for insulin than it otherwise would have paid absent Defendants' conduct.

40. Plaintiff seeks to recover for the losses it has suffered due to Defendants' illegal Insulin Pricing Scheme.

B. Manufacturer Defendants

41. **Defendant Eli Lilly and Company ("Eli Lilly")** is an Indiana corporation with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

42. Eli Lilly is registered to do business in the State of Tennessee. Eli Lilly may be served through its registered agent: National Registered Agents, Inc., 300 Montvue Road, Knoxville, Tennessee 37919-5546.

43. In Tennessee and nationally, Eli Lilly manufactures, promotes, and distributes several at-issue diabetes medications: Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.

44. Eli Lilly's global revenues in 2019 were $4.13 billion from Trulicity, $2.82 billion from Humalog, $1.29 billion from Humulin and $1.11 billion from Basaglar.

45. Eli Lilly's global revenues in 2018 were $3.2 billion from Trulicity, $2.99 billion from Humalog, $1.33 billion from Humulin and $801 million from Basaglar.

46. Eli Lilly transacts business in Tennessee and in Cocke County, targeting these markets for its products, including the at-issue diabetes medications.

47. Eli Lilly employs sales representatives throughout Tennessee to promote and sell Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.

48. Eli Lilly also directs advertising and informational materials to Tennessee and Cocke County physicians and potential users of Eli Lilly's products.

49. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Eli Lilly published its prices for the at-issue diabetes medications throughout Tennessee with the express knowledge that payment and reimbursement by Plaintiff would be based on those false list prices.

50. During the relevant time period, Plaintiff purchased Eli Lilly's at-issue drugs at a price based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

51. All of the Eli Lilly diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee based on the specific false and inflated prices Eli Lilly caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

52. **Defendant Sanofi-Aventis U.S. LLC ("Sanofi")** is a Delaware limited liability company with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

53. Sanofi may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

54. Sanofi manufactures, promotes, and distributes pharmaceutical drug both in Tennessee and nationally, including several at-issue diabetes medications: Lantus, Toujeo, Soliqua, and Apidra.

55. Sanofi's global revenues in 2019 were $3.50 billion from Lantus and $1.03 billion from Toujeo, $400 million from Apidra and $144 million from Soliqua.

56. Sanofi's global revenues in 2018 were $3.9 billion from Lantus, $923 million from Toujeo, $389 million from Apidra and $86 million from Soliqua.

57. Sanofi does business in Tennessee and in Cocke County, targeting these markets for its products, including the at-issue diabetes medications.

58. Sanofi employs sales representatives throughout Tennessee and in this District to promote and sell Lantus, Toujeo, Soliqua, and Apidra.

59. Sanofi also directs advertising and informational materials to Tennessee physicians and potential users of Sanofi's products for the specific purpose of selling the at-issue drugs in Tennessee and Cocke County and profiting from the Insulin Pricing Scheme.

60. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Sanofi published its prices of its at-issue diabetes medications throughout Tennessee for the purpose of payment and reimbursement by payors, including Plaintiff.

61. During the relevant time period, Plaintiff Cocke County purchased Sanofi's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

62. All of the Sanofi diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee and Cocke County based on the specific false and inflated prices Sanofi caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

63. **Defendant Novo Nordisk Inc. ("Novo Nordisk")** is a Delaware corporation with its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

64. Novo Nordisk is registered to do business in the State of Tennessee. Novo Nordisk may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

65. Novo Nordisk manufactures, promotes, and distributes pharmaceutical drugs both in Tennessee and nationally, including at-issue diabetic medications: Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.

66. Nordisk's global revenues in 2019 were $2.89 billion from Novolog, $973 million from Levemir, $968 million from Tresiba, $2.29 billion from Victoza and $1.17 billion from Ozempic.[13]

67. Novo Nordisk's global revenues in 2018 were $4.19 billion from Novolog, $1.66 billion from Levemir, $1.19 billion from Tresiba, $3.61 billion from Victoza and $185 million from Ozempic.

68. Novo Nordisk transacts business in Tennessee and in Cocke County, targeting these markets for its products, including the at-issue diabetes medications.

69. Novo Nordisk employs sales representatives throughout Tennessee and Cocke County to promote and sell Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.

70. Novo Nordisk also directs advertising and informational materials to Tennessee and Cocke County physicians and potential users of Novo Nordisk's products.

71. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Novo Nordisk published its prices of its at-issue diabetes medications throughout Tennessee for the purpose of payment and reimbursement by Plaintiff.

72. During the relevant time period, Plaintiff purchased Novo Nordisk's at-issue diabetes medications at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

[13] Novo Nordisk, Annual Report (Form 20-F) (Dec. 31, 2019).

73. All Novo Nordisk diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee based on the specific false and inflated prices Novo Nordisk caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

74. Collectively, Defendants Eli Lilly, Novo Nordisk, and Sanofi are referred to as the "Manufacturer Defendants" or the "Manufacturers."

C. PBM Defendants

75. **Defendant CVS Health Corporation ("CVS Health")** is a Delaware corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Health transacts business and has locations throughout the United States and Tennessee.

76. CVS Health may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

77. CVS Health—through its executives and employees, including its CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers—is directly involved in creating and implementing the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs involved in the Insulin Pricing Scheme.

78. CVS Health's conduct had a direct effect in Tennessee and damaged Plaintiff Cocke County as a payor and purchaser.

79. On a regular basis, CVS Health executives and employees communicate with and direct its subsidiaries related to the at-issue PBM services and formulary activities.

80. In each annual report for at least the last decade, CVS Health (or its predecessor) has repeatedly and explicitly stated that CVS Health:

- designs pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients' members;

- negotiates with pharmaceutical companies to obtain discounted acquisition costs for many of the products on CVS Health's drug lists, and these negotiated discounts enable CVS Health to offer reduced costs to clients; and

- utilizes an independent panel of doctors, pharmacists, and other medical experts, referred to as its Pharmacy and Therapeutics Committee, to select drugs that meet the highest standards of safety and efficacy for inclusion on its drug lists.

81. CVS Health publicly represents that it constructs programs that lower the cost of the at-issue diabetes medications. For example, in 2016, CVS Health announced a new program to "reduce overall spending in diabetes" that is available in all states, including Tennessee, stating:

> *CVS Health* introduced a new program available to help the company's pharmacy benefit management (PBM) clients to improve the health outcomes of their members, *lower pharmacy costs [for diabetes medications]* through aggressive trend management and decrease medical costs . . . [and that] participating clients could save between $3000 to $5000 per year for each member who successfully improves control of their diabetes" (emphasis supplied).[14]

82. In 2017, CVS Health stated that "*CVS Health* pharmacy benefit management (PBM) strategies reduced trend for commercial clients to 1.9 percent per member per year the lowest in five years. Despite manufacturer price increases of near 10 percent, *CVS Health* kept drug price growth at a minimal 0.2 percent."

83. In November 2018, CVS Health acquired Aetna for $69 billion and became the first combination of a major health insurer, PBM, and mail-order and retail pharmacy chain. As a result, CVS Health controls the health plan/insurer, the PBM, and the pharmacies utilized by approximately 40 million Aetna members in the United States, including in Tennessee. CVS Health controls the entire drug pricing chain for these 40 million Americans.

[14] CVS HEALTH, *CVS Health Introduces New "Transform Diabetes Care" Program to Improve Health Outcomes and Lower Overall Health Care Costs* (Dec. 13, 2016), https://cvshealth.com/newsroom/press-releases/cvs-health-introduces-newtransform-diabetes-care-program-improve-health.

84. CVS Health is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Tennessee that dispensed and received payment for the at-issue diabetes medications throughout the relevant time period.

85. **Defendant CVS Pharmacy, Inc. ("CVS Pharmacy")** is a Rhode Island corporation whose principal place of business is at the same location as CVS Health. CVS Pharmacy is a wholly owned subsidiary of CVS Health.

86. CVS Pharmacy is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Tennessee and is directly involved in these pharmacies dispensing and payment policies related to the at issue diabetes medications.

87. CVS Pharmacy is also the immediate and direct parent of Defendant Caremark Rx, LLC.

88. CVS Pharmacy is registered to do business in Tennessee and has been since at least 1997.

89. CVS Pharmacy is registered to do business in the State of Tennessee. CVS Pharmacy may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

90. During the relevant time period, CVS Pharmacy provided retail pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

91. **Defendant Caremark Rx, LLC** is a Delaware limited liability company and an immediate or indirect parent of many subsidiaries, including pharmacy benefit management and mail-order subsidiaries that engaged in the activities in Tennessee that gave rise to this Complaint.

92. Caremark Rx, LLC is a wholly owned subsidiary of Defendant CVS Pharmacy and its principal place of business is at the same location as CVS Pharmacy and CVS Health.

93. Caremark Rx, LLC is registered to do business in Tennessee and has been since at least 2007. Caremark Rx, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

94. During the relevant time period, Caremark Rx, LLC provided PBM and mail order pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme and damaged payors in Tennessee, including Plaintiff.

95. **Defendant Caremark, LLC** is a California limited liability company whose principal place of business is at the same location as CVS Health. Caremark, LLC is a wholly owned subsidiary of Caremark Rx, LLC.

96. Caremark, LLC is registered to do business in Tennessee and has been since at least 2007. Caremark, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

97. During the relevant time period, Caremark, LLC provided PBM and mail order pharmacy services in Tennessee and Cocke County that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

98. **Defendant CaremarkPCS Health, LLC** is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. CVS Health is the direct or indirect parent company of CaremarkPCS Health LLC.

99. CaremarkPCS Health, LLC, doing business as CVS Caremark, provides pharmacy benefit management services.

100. CaremarkPCS Health, LLC is registered to do business in Tennessee and has been since at least 2009. CaremarkPCS Health, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

101. During the relevant time period, CaremarkPCS Health, LLC provided PBM services in the State of Tennessee, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff Cocke.

102. Defendants CaremarkPCS Health, LLC and Caremark, LLC are agents and/or alter egos of Caremark Rx, LLC, CVS Pharmacy, and CVS Health.

103. As a result of numerous interlocking directorships and shared executives, Caremark Rx, LLC, CVS Pharmacy, and CVS Health are directly involved in the conduct of and control CaremarkPCS Health, LLC and Caremark, LLC's operations, management, and business decisions related to the at-issue formulary construction; Manufacturer Payments; and mail-order and retail pharmacy services—to the ultimate detriment of Plaintiff. For example:

a. During the relevant time period, these parent and subsidiaries have had common officers and directors, including:

- Thomas S. Moffatt, Vice President and Secretary of Caremark Rx, LLC, CaremarkPCS Health LLC, and Caremark, LLC, is also a Vice President, Assistant Secretary, and Senior Legal Counsel at CVS Health and the Vice President, Secretary and Senior Legal Counsel of CVS Pharmacy;

- Melanie K. Luker, Assistant Secretary of Caremark Rx, LLC, CaremarkPCS Health, LLC, and Caremark, LLC, is also a Manager of Corporate Services at CVS Health;

- Carol A. Denale, Senior Vice President and Treasurer of Caremark Rx, LLC, is also Senior Vice President, Treasurer and Chief Risk Officer at CVS Health Corporation;

- John M. Conroy has been Vice President of Finance at CVS Health since 2011, and was also President and Treasurer of Caremark, LLC and CaremarkPCS Health LLC in 2019; and

- Sheelagh Beaulieu has been the Senior Director of Income Tax at CVS Health while also acting as the Assistant Treasurer at CaremarkPCS Health LLC and Caremark LLC.

b. CVS Health owns all the stock of CVS Pharmacy, which, in turn, owns all the stock of Caremark Rx, LLC, which, in turn, owns all the stock of Caremark LLC. CVS Health also directly or indirectly owns all the stock of CaremarkPCS Health LLC.

c. CVS Health, as a corporate family, does not operate as separate entities. The public filings, documents, and statements of CVS Health present its subsidiaries, including CVS Pharmacy, CaremarkPCS Health, LLC, Caremark, LLC and Caremark Rx, LLC as divisions or departments of one unified "diversified health services company" that "works together across our disciplines" to "create unmatched human connections to transform the health care experience." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations discussed in this Complaint.[15]

d. All executives of CaremarkPCS Health, LLC, Caremark, LLC, Caremark Rx, LLC, and CVS Pharmacy ultimately report to the executives at CVS Health, including the President and CEO of CVS Health.

e. As stated above, CVS Health's CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers are directly involved in the policies and business decisions of CaremarkPCS Health, LLC and Caremark, LLC that gave rise to Plaintiff Cocke County's claims in this Complaint.

[15] CVS Caremark/CVS Health, Annual Report (Form 10-K) (Dec. 31, 2009-2019); CVS Health, *Our Purpose*, https://cvshealth.com/about-cvs-health/our-purpose (last visited Sept. 9, 2022); CVS Health, *Quality of Care*, https://cvshealth.com/health-withheart/improving-health-care/quality-of-care (last visited Sept. 9, 2022).

104. Collectively, Defendants CVS Health, CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC and CaremarkPCS Health, LLC, including all predecessor and successor entities, are referred to as "CVS Caremark."

105. CVS Caremark is named as a Defendant in its capacities as a PBM and pharmacy.

106. In its capacity as a PBM, CVS Caremark coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on CVS Caremark's formularies.

107. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing approximately 40% of the national market. CVS Caremark's pharmacy services segment generated $141.5 billion in total revenues last year.

108. At all times relevant hereto, CVS Caremark offered pharmacy benefit services nationwide and to Tennessee payors, and derived substantial revenue therefrom, and, in doing so, made the at-issue misrepresentations (discussed below) and utilized the false prices generated by the Insulin Pricing Scheme to unlawfully profit off of payors like Plaintiff.

109. At all times relevant hereto, CVS Caremark offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

110. CVS Caremark purchases drugs directly from manufacturers and through drug wholesalers for dispensing through its mail-order pharmacy.

111. During the relevant time period, CVS Caremark provided PBM services to Plaintiff and, in doing so, CVS Caremark set the price that Plaintiff paid for the at-issue drugs based on the

false list prices generated by the Insulin Pricing Scheme. Plaintiff paid CVS Caremark for the at-issue drugs.

112. In its capacity as a retail pharmacy, CVS Caremark further and knowingly profited from the false list prices produced by the Insulin Pricing Scheme by pocketing the spread between acquisition cost for the drugs at issue (an amount well below the list price generated by the Insulin Pricing Scheme), and the amounts it received from payors (which amounts were based on the false list prices and, in many cases, were set by CVS Caremark in its capacity as a PBM).

113. During the relevant time period, CVS Caremark provided mail-order and retail pharmacy services to Plaintiff and, in doing so, Plaintiff paid CVS Caremark for the at-issue drugs at prices based on the false list prices generated by the Insulin Pricing Scheme.

114. At all times relevant hereto, CVS Caremark dispensed the at-issue medications nationwide and directly to Plaintiff through its mail-order and retail pharmacies and derived substantial revenue from these activities in Tennessee.

115. At all times relevant hereto, CVS Caremark had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to CVS Caremark, as well as agreements related to the Manufacturers' at-issue drugs sold through CVS Caremark's mail-order pharmacies.

116. **Defendant Evernorth Health, Inc. ("Evernorth")**, formerly known as Express Scripts Holding Company, is a Delaware corporation with its principal place of business at 1 Express Way, St. Louis, Missouri 63121.[16]

[16] Until 2021, Evernorth Health, Inc. conducted business under the name Express Scripts Holding Company. For the purposes of this Complaint "Evernorth" refers to Evernorth Health, Inc and Express Scripts Holding Company.

117. Evernorth may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

118. Evernorth, through its executives and employees, including its CEO and Vice Presidents, is directly involved in shaping the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs, related to the Insulin Pricing Scheme.

119. Evernorth's conduct had a direct effect in Tennessee and with respect to Plaintiff Cocke County.

120. On a regular basis, Evernorth executives and employees communicate with and direct Evernorth's subsidiaries related to the at-issue PBM services and formulary activities.

121. Evernorth is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Tennessee, which engaged in the activities that gave rise to this Complaint.

122. In December 2018, Evernorth merged with Cigna in a $67 billion deal to consolidate their businesses as a major health insurer, PBM, and mail-order pharmacy. As a result, the Evernorth corporate family controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 15 million Cigna members in the United States, including in Tennessee. Evernorth controls the entire drug pricing chain for these 15 million Americans.

123. In each annual report for at least the last decade, Evernorth has repeatedly and explicitly:

- Acknowledged that it is directly involved in the company's PBM services, stating "[Evernorth is] the largest stand-alone PBM company in the United States."

- Stated that Evernorth: "provid[es] products and solutions that focus on improving patient outcomes and assist in controlling costs; evaluat[es] drugs for efficacy, value and price to assist clients in selecting a cost-effective formulary; [and] offer[s] cost-effective home delivery pharmacy and specialty services that result in cost savings for plan sponsors and better care for members."

124. **Defendant Express Scripts, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts, Inc.'s principal place of business is the same location as Evernorth.

125. Express Scripts, Inc. is registered to do business in Tennessee and has been since at least 2017. Express Scripts, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 39719-5546.

126. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Tennessee that engaged in the conduct that gave rise to this Complaint.

127. During the relevant time period, Express Scripts Inc. was directly involved in the PBM and mail-order pharmacy services that gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

128. Indeed, Express Scripts, Inc. provided pharmacy benefit services to Plaintiff, based on Plaintiff's reliance upon Express Scripts, Inc.'s response to Plaintiff's Request for Proposals.

129. **Defendant Express Scripts Administrators, LLC**, doing business as Express Scripts and formerly known as Medco Health, LLC, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth. Express Scripts Administrators, LLC's principal place of business is at the same location as Evernorth.

130. Express Scripts Administrators, LLC is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

131. During the relevant time period, Express Scripts Administrators, LLC provided the PBM services in Tennessee discussed in this Complaint that gave rise to the Insulin Pricing Scheme that damaged Plaintiff.

132. **Defendant Medco Health Solutions, Inc. ("Medco")** is a Delaware Corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey.

133. Medco is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

134. In 2012, Express Scripts acquired Medco for $29 billion.

135. Prior to the merger, Express Scripts and Medco were two of the largest PBMs in the United States and in Tennessee.

136. Prior to the merger, Medco provided the at-issue PBM and mail-order services, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff, within Tennessee.

137. Following the merger, all of Medco's PBM and mail-order pharmacy functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco's payor customers becoming Express Scripts' customers. The combined company covered over 155 million lives at the time of the merger.

138. At the time of the merger, on December 6, 2011, in his testimony before the Senate Judiciary Committee, David B. Snow, the then-CEO of Medco, publicly represented that "the merger of Medco and Express Scripts will result in immediate savings to our clients and, ultimately, to consumers. This is because our combined entity will achieve even greater [Manufacturer Payments] from drug manufacturers and other suppliers."

139. The then-CEO of Express Scripts, George Paz, during a Congressional subcommittee hearing in September 2011, echoed these sentiments: "A combined Express Scripts and Medco will be well-positioned to protect American families from the rising cost of prescription medicines."

140. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. ESI Mail Pharmacy Service, Inc.'s principal place of business is the same location as Evernorth.

141. ESI Mail Pharmacy Service, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

142. During the relevant time period, ESI Mail Pharmacy Services provided the mail-order pharmacy services in Tennessee discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

143. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts Pharmacy, Inc.'s principal place of business is at the same location as Evernorth.

144. Express Scripts Pharmacy, Inc. is registered to do business in Tennessee and has been since 2021. Express Scripts Pharmacy, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

145. During the relevant time period, Express Scripts Pharmacy, Inc. provided the mail-order pharmacy services in Tennessee discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

146. As a result of numerous interlocking directorships and shared executives, Evernorth and Express Scripts, Inc. control Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail-order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. During the relevant time period, these parent and subsidiaries have had common officers and directors:

- Officers and/or directors shared between Express Scripts, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; David Queller, President; Jill Stadelman, Managing Counsel; and Scott Lambert, Treasury Manager Director;
- Executives shared between Express Scripts Administrators, LLC and Evernorth include Bradley Phillips, Chief Financial Officer; and Priscilla Duncan, Associate Senior Counsel;
- Officers and/or directors shared between ESI Mail Pharmacy Service, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Priscilla Duncan, Associate Senior Counsel; and Joanne Hart, Treasury Director; and
- Officers and/or directors shared between Express Scripts Pharmacy, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Jill Stadelman, Managing Counsel; Scott Lambert, Treasury Manager Director; and Joanne Hart, Treasury Director.

b. Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc.

c. The Evernorth corporate family does not operate as separate entities. The public filings, documents, and statements of Evernorth present its subsidiaries, including Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc., as divisions or departments of a single company that "unites businesses that have as many as 30+ years of experience . . . to

take health services further with integrated data and analytics that help us deliver better care to more people." The day-to-day operations of this corporate family reflect these public statements. All of these entities comprise a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint. All of the executives of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. ultimately report to the executives, including the CEO, of Evernorth.

d. As stated above, Evernorth's CEO and other executives and officers are directly involved in the policies and business decisions of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. that gave rise to Plaintiff's claims in this Complaint.

147. Collectively, Defendants Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc., including all predecessor and successor entities, are referred to as "Express Scripts."

148. Express Scripts is named as a Defendant in its capacities as a PBM and mail order pharmacy.

149. In its capacity as a PBM, Express Scripts coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on Express Script's formularies.

150. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States. During the relevant period of this Complaint, Express Scripts controlled

30% of the PBM market in the United States. Express Scripts has only grown larger since the Cigna merger.

151. In 2017, annual revenue for Express Scripts was over $100 billion.

152. As of December 31, 2018, more than 68,000 retail pharmacies, representing over 98% of all retail pharmacies in the nation, participated in one or more of Express Scripts' networks.

153. Express Scripts transacts business throughout the United States and Tennessee.

154. At all times relevant hereto, Express Scripts derived substantial revenue providing pharmacy benefits in Tennessee.

155. At all times relevant hereto, and contrary to their express representations, Express Scripts knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

156. At all times relevant hereto, Express Scripts concealed its critical role in the generation of those false list prices.

157. At all times relevant hereto, Express Scripts maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications.

158. During the relevant time period, Express Scripts provided PBM services to Plaintiff and, in doing so, Express Scripts set the price that Plaintiff paid for the at-issue drugs, at prices based on the false list prices generated by the Insulin Pricing Scheme, and Plaintiff paid Express Scripts for the at-issue drugs.

159. In its capacity as a mail-order pharmacy, Express Scripts received payments from Tennessee payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices generated by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

160. At all times relevant hereto, Express Scripts offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

161. Express Scripts purchases drugs directly from manufacturers for dispensing through its mail-order pharmacy.

162. At all times relevant hereto, Express Scripts dispensed the at-issue medications nationwide and directly to Plaintiff through its mail-order pharmacies and derived substantial revenue from these activities in Tennessee.

163. During the relevant time period, in addition to its critical role in the Insulin Pricing Scheme, which detrimentally affected all payors and purchasers of the at-issue drugs, Express Scripts also provided PBM services directly to Plaintiff Cocke County.

164. During the years when some of the largest at-issue price increases occurred, Express Scripts worked directly with OptumRx to negotiate Manufacturer Payments on behalf of OptumRx and its clients in exchange for preferred formulary placement.

165. For example, in a February 2014 email released by the U.S. Senate in conjunction with its January 2021 report titled “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug” (“January 2021 Senate Insulin Report”), Eli Lilly describes a “Russian nested

doll situation" in which Express Scripts was negotiating rebates on behalf of OptumRx related to the at-issue drugs for Cigna (who later would become part of Express Scripts).[17]

166. At all times relevant hereto, Express Scripts had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to Express Scripts, as well as agreements related to the Manufacturers' at-issue drugs sold through Express Scripts' mail-order pharmacies.

167. **Defendant UnitedHealth Group, Inc**. is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343.

168. UnitedHealth Group, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

169. UnitedHealth Group, Inc. is a diversified managed healthcare company. In 2015, UnitedHealth Group reported revenue in excess of $257 billion, and the company is currently ranked sixth on the Fortune 500 list. UnitedHealth Group, Inc. offers a spectrum of products and services including health insurance plans through its wholly owned subsidiaries and prescription drugs through its PBM, OptumRx.

170. Over one-third of the overall revenues of UnitedHealth Group come from OptumRx.

[17] CHARLES E. GRASSLEY & RON WYDEN, STAFF REPORT ON INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG, S. FIN. COMM., https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf; Letter from Joseph B. Kelley, Eli Lilly Vice President, Global Gov. Affairs, to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Eli%20Lilly_Redacted%20v1.pdf

171. UnitedHealth Group, through its executives and employees, is directly involved in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme. For example, UnitedHealth Group executives structure, analyze, and direct the company's overarching policies, including with respect to PBM and mail-order services, as a means of maximizing profitability across the corporate family.

172. UnitedHealth Group's Sustainability Report states that "OptumRx works directly with pharmaceutical manufacturers to secure discounts that lower the overall cost of medications and create tailored formularies – or drug lists – to ensure people get the right medications. [*UnitedHealth Group*] then negotiate[s] with pharmacies to lower costs at the point of sale . . . [*UnitedHealth Group*] also operate[s] [mail-order pharmacies] . . .. [*UnitedHealth Group*] work[s] directly with drug wholesalers and distributors to ensure consistency of the brand and generic drug supply, and a reliance on that drug supply."

173. In addition to being a PBM and a mail-order pharmacy, UnitedHealth Group owns and controls a major health insurance company, UnitedHealthcare. As a result, UnitedHealth Group controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 26 million UnitedHealthcare members in the United States, including those in Tennessee. UnitedHealth Group controls the entire drug pricing chain for these 26 million Americans.

174. UnitedHealth Group's conduct had a direct effect in Tennessee and damaged Plaintiff.

175. UnitedHealth Group states in its Annual Reports that UnitedHealth Group "utilizes Optum's capabilities to help coordinate patient care, improve affordability of medical care, analyze

cost trends, manage pharmacy benefits, work with care providers more effectively and create a simpler consumer experience."

176. **Defendant Optum, Inc.** is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing subsidiaries that administer pharmacy benefits, including Defendant OptumRx, Inc.

177. Optum, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

178. Optum, Inc. is directly involved, through its executives and employees, in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme, which had a direct effect in Tennessee and damaged Plaintiff.

179. For example, according to Optum Inc.'s press releases, Optum, Inc. is "UnitedHealth Group's information and technology-enabled health services business platform serving the broad healthcare marketplace, including care providers, plan sponsors, payors, life sciences companies and consumers."[18] In this role Optum, Inc. is directly responsible for the "business units – OptumInsight, OptumHealth and OptumRx"[19] and the CEOs of all these companies report directly to Optum, Inc. regarding their policies, including those that inform the at-issue formulary construction and mail order activities.

180. **Defendant OptumRx, Inc.** is a California corporation with its principal place of business at 2300 Main Street, Irvine, California, 92614.

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[18] UNITEDHEALTH GROUP, https://www.unitedhealthgroup.com/ (last visited on Sept. 9, 2022); *UnitedHealth Group Announces "Optum" Master Brand for Its Health Services Businesses*, FIERCE HEALTHCARE (Apr. 11, 2011, 9:21 AM), https://www.fiercehealthcare.com/healthcare/unitedhealth-group-announces-optummaster-brand-for-its-health-services-businesses.

[19] *Id.*; UNITEDHEALTH GROUP, *UnitedHealth Group Announces "Optum" Master Brand for Its Health Services Businesses* (Apr. 11, 2011), https://www.unitedhealthgroup.com/newsroom/2011/0411optum.html.

181. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings I, LLC, which, in turn, operates as a subsidiary of Defendant Optum, Inc.

182. OptumRx, Inc. is registered to do business in Tennessee and has been since at least 2008. OptumRx, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

183. During the relevant time period, OptumRx, Inc. provided the PBM and mail order pharmacy services to Plaintiff and in Tennessee that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

184. **Defendant OptumInsight, Inc**. is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota.

185. OptumInsight, Inc. is registered to do business in Tennessee and has been since at least 1997. OptumInsight, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

186. OptumInsight, Inc. is an integral part of the Insulin Pricing Scheme and, during the relevant time period coordinated directly with the Manufacturer Defendants in furtherance of the conspiracy. OptumInsight analyzed data and other information from the Manufacturer Defendants to advise the other Defendants with regard to the profitability of the Insulin Pricing Scheme to the benefit of all Defendants.

187. As a result of numerous interlocking directorships and shared executives, UnitedHealth Group, OptumRx Holdings I, LLC, and Optum, Inc are directly involved in the conduct of and control OptumInsight and Optum Rx's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. These parent and subsidiaries have common officers and directors, including:

- Sir Andrew Witty is president of UnitedHealth Group and CEO of Optum, Inc.;
- Dan Schumacher is president of Optum, Inc and is also named to the Office of the Chief Executive at UnitedHealth Group, Inc.;
- Terry Clark is a senior vice president and chief marketing officer at UnitedHealth Group and also oversees the branding, marketing and advertising for UnitedHealth Group and Optum, Inc.;
- Tom Roos serves as chief accounting officer for UnitedHealth Group and Optum, Inc.;
- Heather Lang is Deputy General Counsel, Subsidiary Governance at UnitedHealth Group, Inc. and also Assistant Secretary at OptumRx, Inc.;
- Peter Gill is Vice President at UnitedHealth Group, Inc. and also Treasurer at OptumRx, Inc.;
- John Santelli leads Optum Technology, the leading technology division of Optum, Inc serving the broad customer base of Optum and UnitedHealthcare and also serves as UnitedHealth Group's chief information officer; and
- Eric Murphy is the Chief Growth and Commercial Officer for Optum, Inc. and has also led OptumInsight, Inc.

b. UnitedHealth Group directly or indirectly owns all the stock of Optum, Inc., OptumRx, Inc., and OptumInsight, Inc.;

c. The UnitedHealth Group corporate family does not operate as separate entities. The public filings, documents, and statements of UnitedHealth Group present its subsidiaries, including Optum, Inc., OptumRx, Inc., and OptumInsight as divisions or departments of a single company that is "a diversified family of businesses" and that "leverages core competencies" to "help[] people live healthier lives and help[] make the health system work better for everyone." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business

enterprise and should be treated as such as to all legal obligations detailed in this Complaint.[20]

d. All the executives of Optum, Inc., OptumRx, Inc., and OptumInsight ultimately report to the executives, including the CEO, of UnitedHealth Group.

e. As stated above, UnitedHealth Group's executives and officers are directly involved in the policies and business decisions of Optum, Inc., OptumRx, Inc., and OptumInsight that gave rise to Plaintiff's claims in this Complaint.

188. Collectively, Defendants UnitedHealth Group, Inc., OptumRx, Inc., OptumInsight, Inc. and Optum, Inc., including all predecessor and successor entities, are referred to as "OptumRx."

189. OptumRx is named as a Defendant in its capacities as a PBM and mail-order pharmacy.

190. OptumRx is a pharmacy benefit manager and, as such, coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on OptumRx's drug formularies.

191. OptumRx provides pharmacy care services to more than 65 million people in the nation through a network of more than 67,000 retail pharmacies and multiple delivery facilities.[21]

192. In 2018, OptumRx managed more than $91 billion in pharmaceutical spending, representing 23% of the PBM market in the United States. OptumRx's 2018 revenue was $69 billion.

[20] UnitedHealth Group, Quarterly Report (Form 10-Q) (Mar. 31, 2017).
[21] UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2018).

193. In 2019, OptumRx managed more than $96 billion in pharmaceutical spending, with a revenue of $74 billion.[22]

194. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Tennessee.

195. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

196. At all times relevant hereto, and contrary to their express representations, OptumRx knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

197. At all times relevant hereto, OptumRx concealed its critical role in the generation of those false list prices.

198. In its capacity as a mail-order pharmacy, OptumRx received payments from payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

199. At all times relevant hereto, OptumRx dispensed the at-issue medications nationwide and directly to Plaintiff and Plaintiff's Beneficiaries in Tennessee through its mail-order pharmacies and derived substantial revenue from these activities in Tennessee.

200. OptumRx purchases the Manufacturer Defendants' drugs, including the at issue diabetes medications, for dispensing through its mail-order pharmacies.

[22] UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2019).

201. At all times relevant hereto, OptumRx had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to OptumRx, as well as agreements related to the Manufacturers' at-issue drugs sold through OptumRx's mail-order pharmacies.

202. Collectively, CVS Caremark, Optum Rx, and Express Scripts are referred to as the "PBM Defendants" or the "PBMs."

JURISDICTION AND VENUE

203. This action is directly filed in *In Re: Insulin Pricing Litigation*, MDL No. 3080, which was established on August 3, 2023, pursuant to the United States Judicial Panel on Multidistrict Litigation transfer order, and in accordance with this Court's August 2023 "Instructions for Opening a Case Relevant to MDL 3080". This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 and pursuant to 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer influenced and Corrupt Organizations Act, 18 U.S.C. § 1962, which raises a federal question. This Court has supplemental jurisdiction over the state law claims in this action pursuant to 28 U.S.C. § 1367.

204. There is also federal subject matter jurisdiction over this action because complete diversity exists among the parties, 28 U.S.C. § 1332. The parties are citizens of different states, and the amount in controversy, exclusive of interests or costs, exceeds the sum or value of $75,000.

205. This Court also has personal jurisdiction over all Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Court in a single trial.

206. Venue is proper pursuant to 18 U.S.C. § 1965 because Defendants Sanofi, Novo Nordisk and Medco reside, are found, have an agent, or transact their affairs in this District, and the ends of justice require that any Defendant residing elsewhere be brought before this Court.

207. Venue is also proper in this District pursuant to 28 U.S.C. § 1391(b) and (c) because all Defendants transact business in, are found in, and/or have agents in this District, and because some of the actions giving rise to the Complaint took place within this District.

ADDITIONAL FACTUAL ALLEGATIONS

A. Diabetes and Insulin Therapy

The Diabetes Epidemic

208. Diabetes occurs when a person's blood glucose is too high. In people without diabetes, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to blood glucose. When insulin is lacking or when cells stop responding to insulin, however, blood sugar stays in the bloodstream. Over time, this can cause serious health problems, including heart disease, blindness, and kidney disease.

209. There are two basic types of diabetes: Type 1 and Type 2. Roughly 90-95% of diabetics are Type 2, which develops when a person does not produce enough insulin or has become resistant to the insulin they produce. While Type 2 patients can initially be treated with tablets, in the long term most patients switch to insulin injections.

210. Diabetes has been on the rise for decades. In 1958, only 1.6 million Americans had diabetes. By the turn of the century, that number had grown to over ten million. Fourteen years later, the number had tripled. Today, more than 37 million Americans—approximately 11% of the country—live with the disease.

211. The prevalence of diabetes in Tennessee has increased as well. Over 760,000 Tennessee adults now live with diabetes and hundreds of thousands more have prediabetes.[23]

Insulin: A Century-Old Drug

212. Despite its potentially deadly impact, diabetes is highly treatable. Patients able to follow a prescribed treatment plan consistently may avoid the health complications associated with the disease. Unlike many high-burden diseases, treatment for diabetes has been available for almost a century.

213. In 1922, Frederick Banting and Charles Best, while working at the University of Toronto, pioneered a technique for removing insulin from an animal pancreas that could then be used to treat diabetes. After discovery, Banting and Best obtained a patent and then sold it to the University of Toronto for $1 (equivalent of $14 today), explaining "[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."[24]

214. After purchasing the patent, the University of Toronto contracted with Defendants Eli Lilly and Novo Nordisk to scale their production. Under this arrangement, Eli Lilly and Novo Nordisk were allowed to apply for patents on variations to the manufacturing process.

215. Although early iterations of insulin were immediately perceived as lifesaving, there have been numerous incremental improvements since its discovery.

216. The earliest insulin was derived from animals and, until the 1980s, was the only diabetes treatment.

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[23] https://www.cdc.gov/diabetes/programs/stateandlocal/state-diabetes-profiles/tennessee.html; Tennessee Diabetes Action Legislative Report, Feb. 2021, https://www.capitol.tn.gov/Archives/senate/112GA/committees/health-welfare/2021/Diabetes%20Legislative%20Report_FinalDraft.%2001-29-2021%208%2045%20pm.pdf.

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[24] Jessica DiGiacinto & Valencia Higuera, *Everything You Need to Know About Insulin*, HEALTHLINE (Oct. 5, 2021), http://www.healthline.com/health/type-2-diabetes/insulin; M. BLISS, THE DISCOVERY OF INSULIN (2013).

217. While effective, animal-derived insulin created the risk of allergic reaction. This risk was lessened in 1982 when synthetic insulin, known as human insulin, was developed by Defendant Eli Lilly. Eli Lilly marketed this insulin as Humulin. The development of human insulin benefited heavily from government and non-profit funding through the National Institute of Health and the American Cancer Society.

218. Over a decade later, Eli Lilly released the first analog insulin.

219. Analog insulin is laboratory-grown and genetically altered insulin. Analogs are slight variations on human insulin that make the injected treatment act more like the insulin naturally produced and regulated by the body.

220. Defendant Eli Lilly developed the first analog insulin, Humalog, in 1996.

221. Other rapid-acting analogs are Defendant Novo Nordisk's Novolog and Defendant Sanofi's Apidra, which have similar profiles. Diabetics use these rapid-acting insulins in combination with longer-acting insulins, such as Sanofi's Lantus and Novo Nordisk's Levemir.

222. The Manufacturer Defendants introduced these rapid-acting and long-acting analog insulins between 1996 and 2007.

223. In 2015, Sanofi introduced Toujeo, another long-acting insulin similar to Lantus; however, Toujeo is highly concentrated, making injection volume smaller than Lantus.

224. In 2016, Eli Lilly introduced Basaglar, which is a long-acting insulin biologically similar to Sanofi's Lantus.

225. Even though insulin was first extracted 100 years ago, and despite its profitability, only Defendants Eli Lilly, Novo Nordisk, and Sanofi manufacture insulin for the United States market. This did not occur by chance.

226. Many of the at-issue medications are now off-patent.

227. The Manufacturers maintain market domination through patent "evergreening." Drugs usually face generic competition when their 20-year patents expire. While original insulin formulas may technically be available for generic use, the Manufacturers "stack" patents around the original formulas, making new competition more costly and risky. For example, Sanofi has filed more than 70 patents on Lantus—more than 95% were filed after the drug was approved by the FDA—potentially providing more than three additional decades of patent "protection" for the drug. The market therefore remains highly concentrated.

The Current Insulin Landscape

228. While insulin today is generally safer and more convenient to use than when originally developed in 1922, there remain questions about whether the overall efficacy of insulin has significantly improved over the last twenty years.

229. For example, while long-acting analogs may have certain advantages over human insulins, such as affording more flexibility around mealtime planning, it has yet to be shown that analogs lead to better long-term outcomes. Recent work suggests that older human insulins may work just as well for patients with Type 2 diabetes.

230. Moreover, all insulins at issue have either been available in the same form since the late 1990s/early 2000s or are biologically equivalent to insulins available then.

231. As Dr. Kasia Lipska, a Yale researcher, explained in the Journal of the American Medical Association:

> We're not even talking about rising prices for better products here. I want to make it clear that we're talking about rising prices for the same product . . . there's nothing that's changed about Humalog. It's the same insulin that's just gone up in price and now costs ten times more.[25]

[25] Natalie Shure, *The Insulin Racket*, American Prospect (June 24, 2019), https://prospect.org/health/insulin-racket/ (last visited Jan. 14, 2023).

232. Production costs have also decreased in recent years. A September 2018 study calculated that, based on production costs, a reasonable price for a year's supply of human insulin is $48 to $71 per person and $78 to $133 for analog insulins. Another recent study found that the Manufacturers could profit at as little as $2 per vial.

233. United States diabetics spent an average of $5,705 each for insulin in 2016. According to a 2020 RAND report, the 2018 list price per vial across all forms of insulin was just $12 in Canada and less than $7 in Australia. In the U.S., it was $98.70.

234. While R&D costs often contribute significantly to a drug's price, the initial basic insulin research occurred 100 years ago and its costs have long-since been recouped. Other costs, such as developing the recombinant DNA-fermentation process and the creation of insulin analogs, were incurred decades ago.

Insulin Adjuncts: Type 2 Medications

235. The Manufacturer Defendants have released several non-insulin diabetes medications over the past decade. Novo Nordisk released Victoza in 2010, followed by Trulicity (Eli Lilly), Soliqua (Sanofi), and Ozempic (Novo Nordisk).[26] The following is a list of diabetes medications at issue in this lawsuit:

[26] Victoza, Trulicity, and Ozempic are glucagon-like peptide-1 receptor agonists ("GLP-1") and mimic the GLP-1 hormone produced in the body. Soliqua is a combination long-acting insulin and GLP-1 drug. Each of these drugs can be used in conjunction with insulins to control diabetes.

Table 1: Diabetes medications at issue in this case

Insulin Type	Action	Name	Company	FDA Approval	Current/Recent List Price
Human	*Rapid-Acting*	Humulin R	Eli Lilly	1982	$178 (vial)
		Humulin R 500	Eli Lilly	1982	$1784 (vial), $689 (pens)
		Novolin R	Novo Nordisk	1991	$165 (vial), $312 (pens)
	Intermediate	Humulin N	Eli Lilly	1982	$178 (vial), $566 (pens)
		Humulin 70/30	Eli Lilly	1989	$178 (vial), $566 (pens)
		Novolin N	Novo Nordisk	1991	$165 (vial), $312 (pens)
		Novolin 70/30	Novo Nordisk	1991	$165 (vial), $312 (pens)
Analog	*Rapid-Acting*	Humalog	Eli Lilly	1996	$342 (vial), $636 (pens)
		Novolog	Novo Nordisk	2000	$347 (vial), $671 (pens)
		Apidra	Sanofi	2004	$341 (vial), $658 (pens)
	Long-Acting	Lantus	Sanofi	2000	$340 (vial), $510 (pens)
		Levemir	Novo Nordisk	2005	$370 (vial), $555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2015	$392 (pens)
		Toujeo (Solostar)	Sanofi	2015	$466 (pens), $622 (max pens)
		Tresiba	Novo Nordisk	2015	$407 (vial) $610 (pens – 100u) $732 (pens – 200u)
Type 2 Medications		Trulicity	Eli Lilly	2014	$1013 (pens)
		Victoza	Novo Nordisk	2010	$813 (2 pens) $1220 (3 pens)
		Ozempic	Novo Nordisk	2017	$1022 (pens)
		Soliqua	Sanofi	2016	$928 (pens)

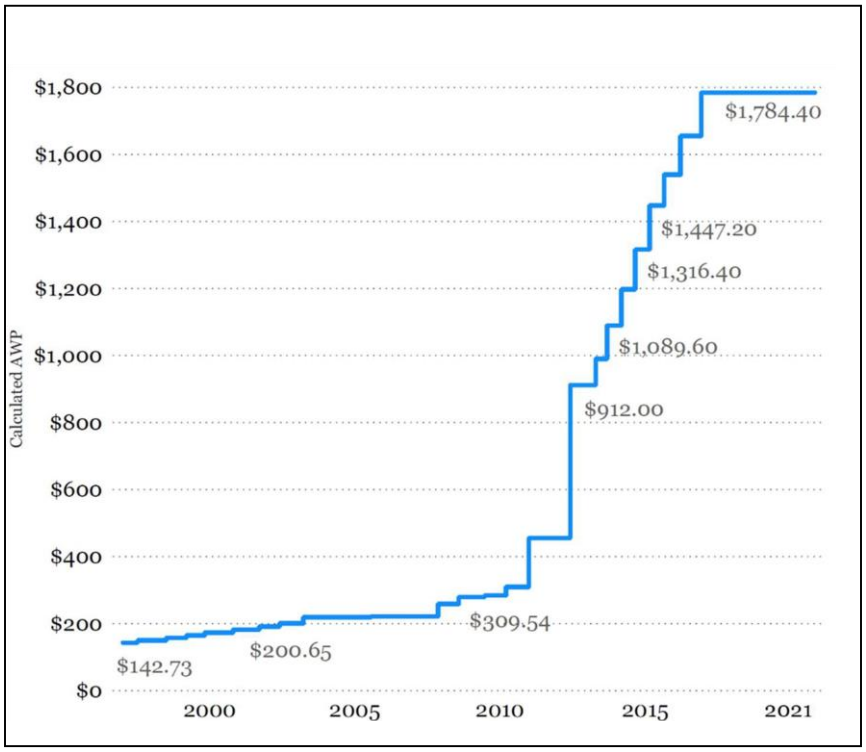
B. The Dramatic Rise in the Price of Diabetes Medications in the U.S.

236. Over the past 25 years, the list price of certain insulins has increased in some cases by more than 1000% (10x).

237. According to the U.S. Bureau of Labor Statistics, $165 worth of consumer goods and services in 1997 dollars would, in 2021, have cost $289 (1.75x).[27]

238. Since 1997, Eli Lilly has raised the list price of a vial of Humulin R (500U/mL) from $165 to $1784 in 2021 (10.8x).

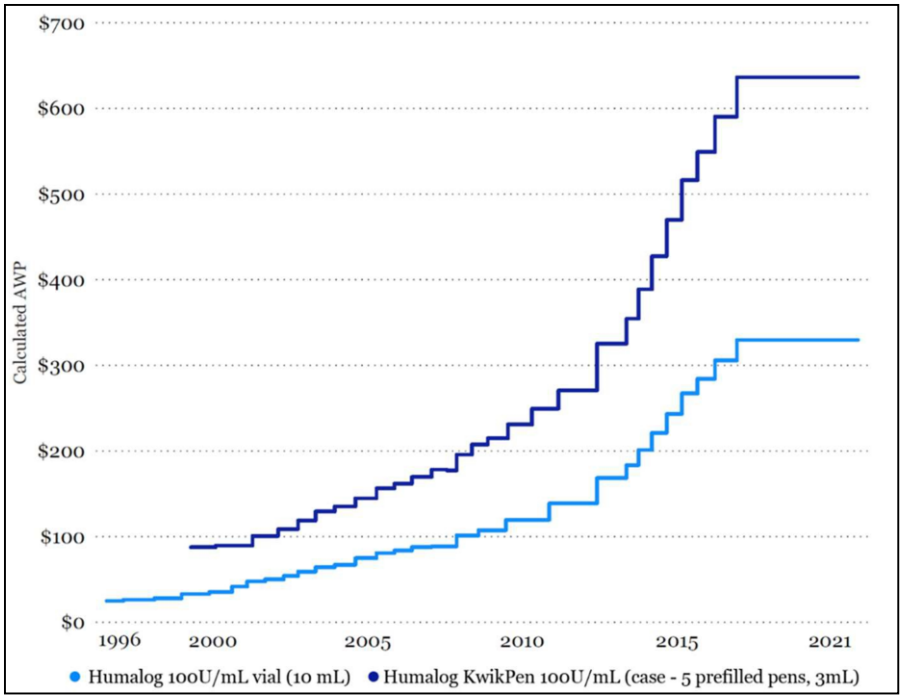
Figure 3: Rising list prices of Humulin R (500U/mL) from 1997-2021



239. Since 1996, Eli Lilly has raised the price for a package of Humalog pens from less than $100 to $663 (6.6x) and from less than $50 per vial to $342 (6.8x). (See Fig. 4.)

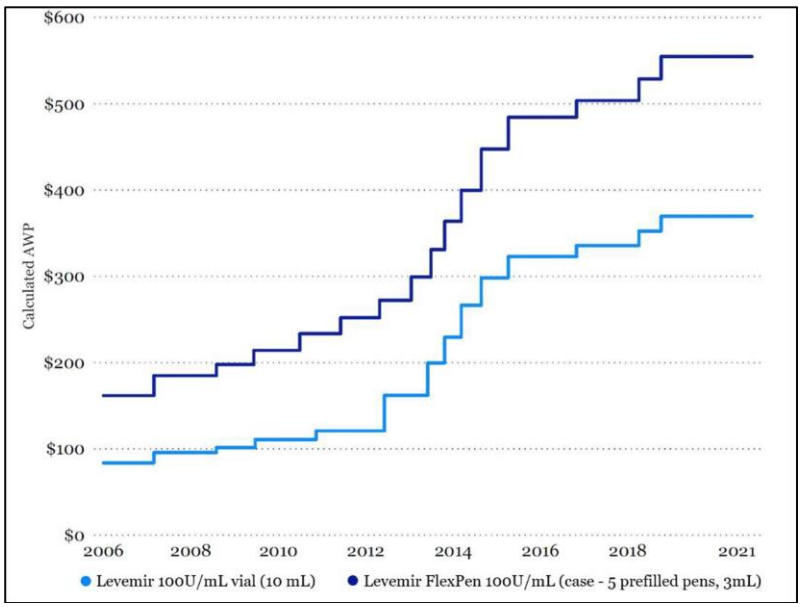
Figure 4: Rising list prices of Humalog vials and pens from 1996-2021

[27] https://www.bls.gov/data/inflation_calculator.htm (last visited Aug. 23, 2023). The Consumer Price Index (CPI) measures "the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services." (https://www.bls.gov/cpi/).



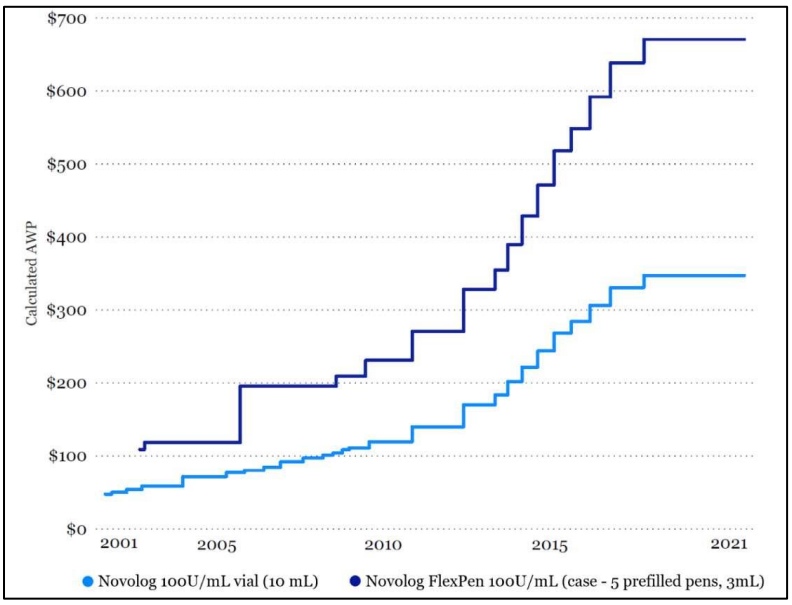
240. From 2006 to 2020, Novo Nordisk has raised Levemir's list price from $162 to $555 (3.4x) for pens and from under $100 to $370 per vial (3.7x).

Figure 5: Rising list prices of Levemir from 2006-2021



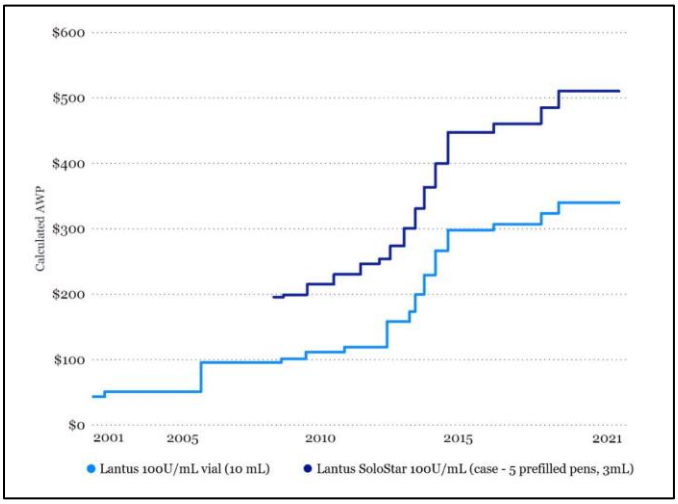
241. From 2002 to 2021, Novo Nordisk raised the list price of Novolog from $108 to $671 (6.2x) for a package of pens and from less than $50 to $347 (6.9x) for a vial.

Figure 6: Rising list prices of Novolog vials and pens from 2002-2021



242. Defendant Sanofi has kept pace. It manufactures a top-selling analog insulin—Lantus—which has been and remains a flagship brand for Sanofi. It has been widely prescribed nationally and within Tennessee, including to Plaintiff's Beneficiaries. Sanofi has raised the list prices for Lantus from less than $200 in 2006 to over $500 in 2020 (2.5x) for a package of pens and from less than $50 to $340 for a vial (6.8x). (See Fig. 7.)

Figure 7: Rising list prices of Lantus vials and pens from 2001-2021



243. The Manufacturer Defendants have similarly ballooned the prices for noninsulin diabetes medications.

244. Driven by these price hikes, payors' and diabetics' spending on these drugs has steadily increased with totals in the tens of billions of dollars. The Defendant-Manufacturers Have Increased Prices in Lockstep

245. The timing of the price increases reveals that the Manufacturer Defendants have not only dramatically increased prices for the at-issue diabetes treatments, but have done so in lockstep.

246. Between 2009 and 2015, for example, Sanofi and Novo Nordisk raised the list prices of their insulins in tandem 13 times, taking the same price increase down to the decimal point within a few days of each other (sometimes within a few hours).[28]

247. This conduct is known as "shadow pricing," which communicates between competitors their intention not to price compete against one another.

[28] Grassley & Wyden, *supra* note 2.

248. In 2016, Novo Nordisk and Sanofi's lockstep increases for the at-issue drugs represented the highest drug price increases in the pharmaceutical industry.

249. Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figure 8 demonstrates this collusive behavior with respect to Lantus and Levemir. Figure 9 demonstrates this behavior with respect to Novolog and Humalog.

Figure 8: Rising list prices of long-acting insulins

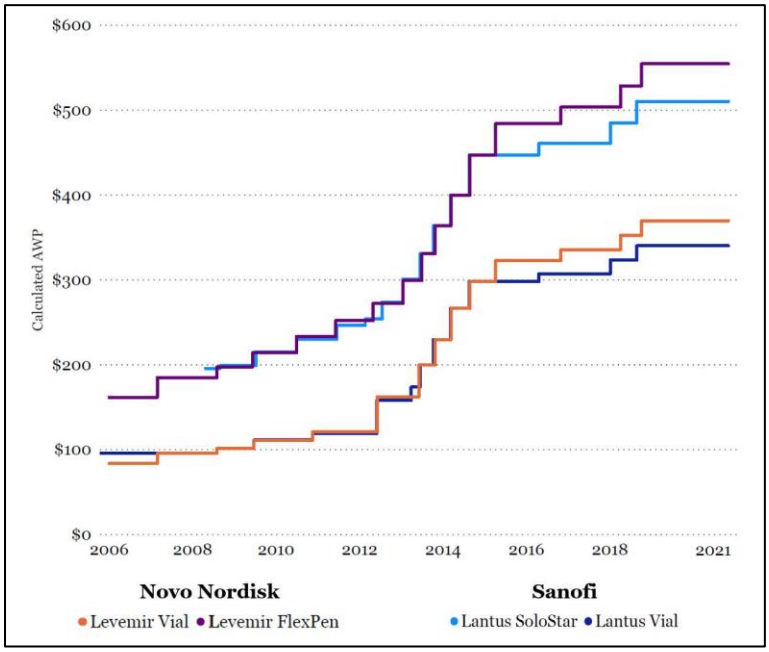
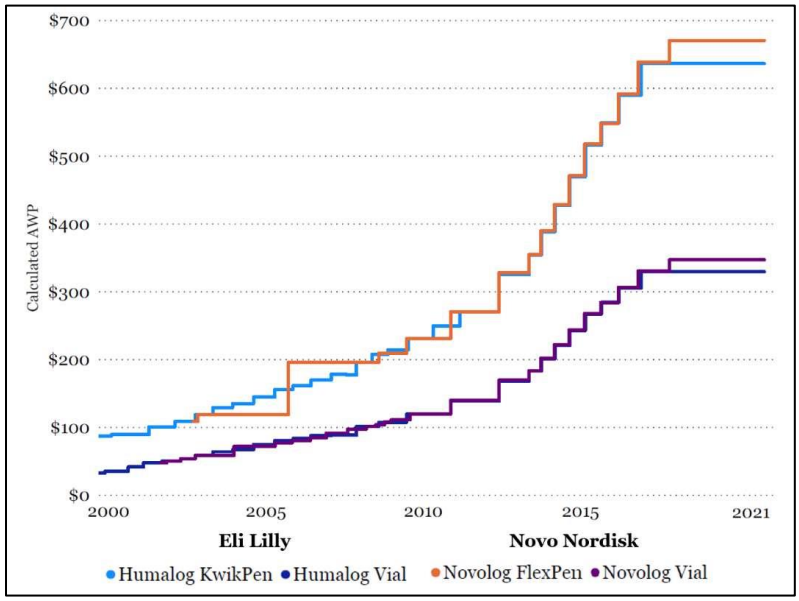
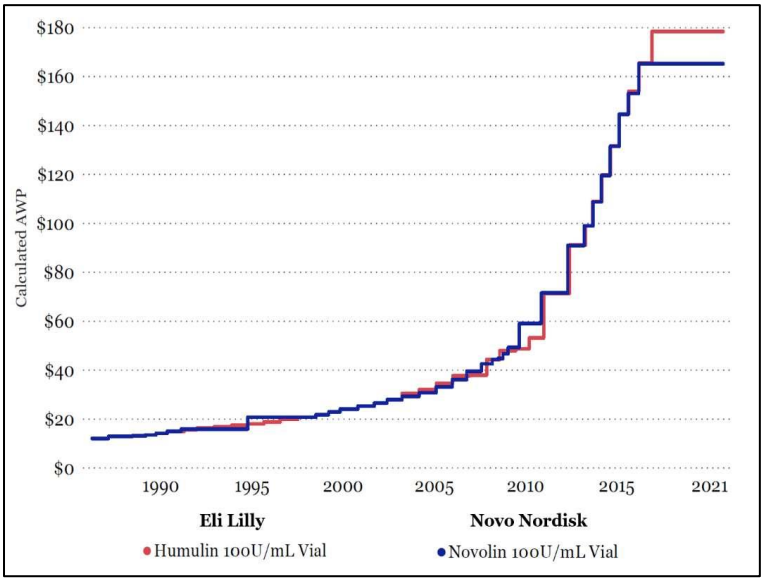


Figure 9: Rising list prices of rapid-acting insulins



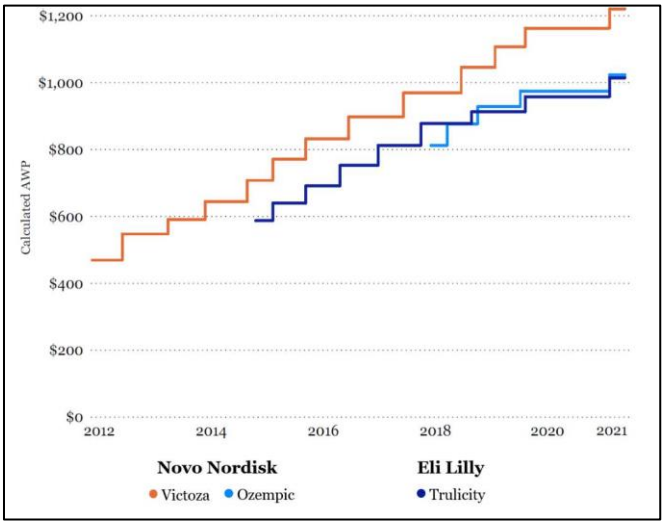
250. Figure 10 below demonstrates this behavior with respect to the human insulins—Eli Lilly's Humulin and Novo Nordisk's Novolin.

Figure 10: Rising list price increases for human insulins



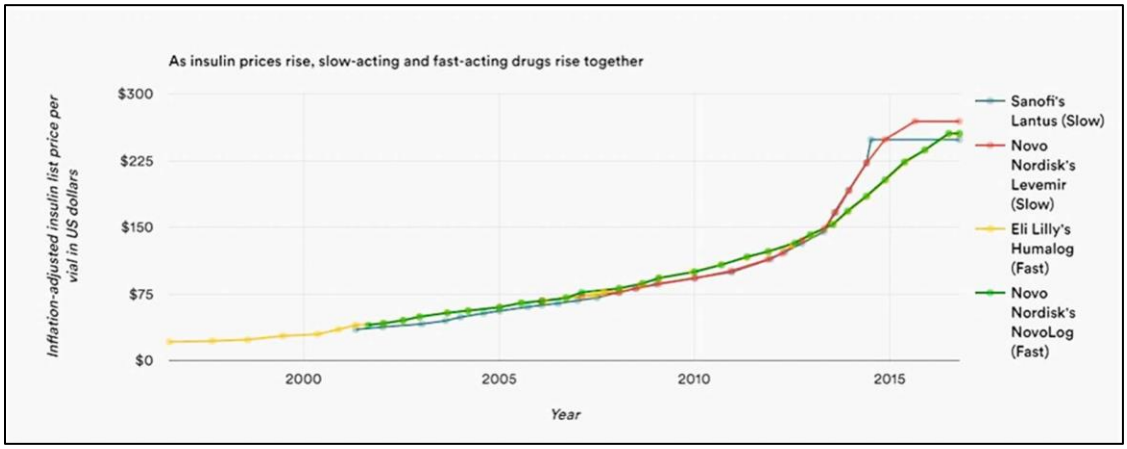
251. Figure 11 below demonstrates Novo Nordisk and Eli Lilly's lockstep price increases for their Type 2 drugs Trulicity, Victoza, and Ozempic.

Figure 11: Rising list prices of Type 2 drugs



252. Figure 12 below shows how, collectively, the Manufacturer Defendants have exponentially raised the prices of insulin products in near-perfect unison.

Figure 12: Lockstep insulin price increases



253. Because of the Manufacturer Defendants' collusive price increases, nearly a century after the discovery of insulin, diabetes medications have become unaffordable for many diabetics.

C. Pharmaceutical Payment and Supply Chain

254. The prescription drug industry is comprised of a deliberately opaque network of entities engaged in multiple distribution and payment structures. These entities include drug manufacturers, wholesalers, pharmacies, health plans/third-party payors, PBMs, and patients.

255. Given the complexities of the different parties involved in the pharmaceutical industry, there are many ways in which pharmaceutical drugs are distributed. Generally speaking, branded prescription drugs, such as the at-issue diabetes medications, are often distributed in one of three ways: (1) from manufacturer to wholesaler (distributor), wholesaler to pharmacy, and pharmacy to patient; (2) from manufacturer to mail-order pharmacy to patient; and (3) from manufacturer to mail-order pharmacy, mail-order pharmacy to self-insured payor, and then self-insured payor to patient.

256. The pharmaceutical industry, however, is unique in that the pricing chain is distinct from the distribution chain. The prices for the drugs distributed in the pharmaceutical chain are different for each participating entity, i.e., different actors pay different prices set by different entities for the same drugs. The unifying factor is that the price that each entity in the pharmaceutical chain pays for a drug is inexorably tied to the price set by the manufacturer. The pricing chain includes self-insured payors paying PBMs directly.

257. There is no transparency in this pricing system. Typically, only a brand drug's list price—also known as its Average Wholesale Price (AWP) or the mathematically related Wholesale Acquisition Cost (WAC)—is available.

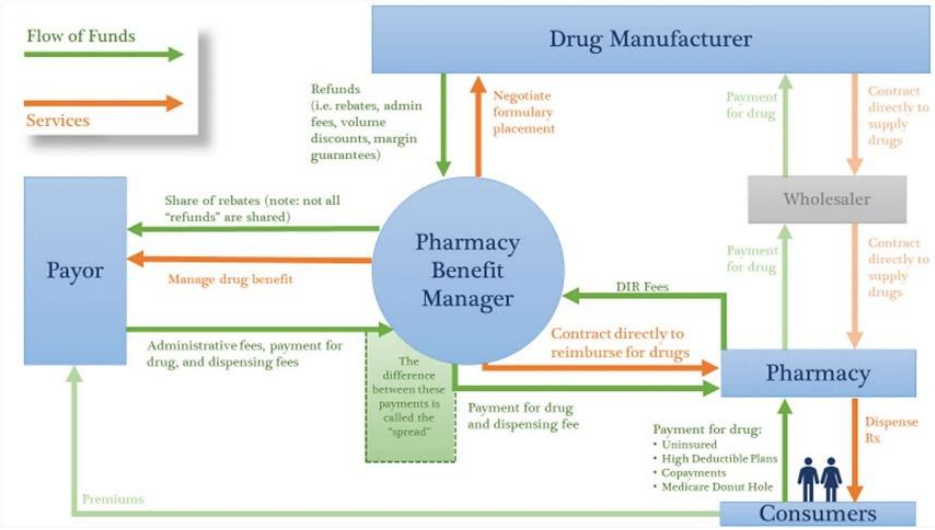
258. Drug manufacturers self-report AWP, or other prices upon which AWP is based, to publishing compendiums such as First DataBank, Redbook, and others who then publish those prices.

259. As a direct result of the PBMs' conduct, AWP persists as the most commonly and continuously used list price in reimbursement and payment calculations and negotiations for both payors and patients.

D. The PBMs' Role in the Pharmaceutical Payment Chain

260. The PBMs are at the center of this convoluted pharmaceutical payment chain, as illustrated in Figure 13 below.

Figure 13: Insulin distribution and payment chain



261. The PBM Defendants develop drug formularies, process claims, create a network of retail pharmacies, set the prices in coordination with the Manufacturers that the payor will pay for prescription drugs, and are paid by the payor to reimburse pharmacies for the drugs utilized by the payor's beneficiaries.

262. The PBMs also contract with a network of retail pharmacies. Pharmacies agree to dispense drugs to patients and pay fees back to the PBMs. The PBMs reimburse pharmacies for the drugs dispensed.

263. The PBM Defendants also own mail-order and specialty pharmacies, which purchase and take possession of prescription drugs, including those at-issue here, and directly supply those drugs to payors like Plaintiff Cocke County, their Beneficiaries, and other patients, by mail.

264. Often, the PBM Defendants purchase drugs directly from the Manufacturers and distribute them directly to the patients. The prices that the PBM Defendants pay are significantly less than the purchase prices paid by payors.

265. Even where PBM Defendant mail-order pharmacies purchase drugs from wholesalers, their costs are set by direct contracts with the manufacturers.

266. In addition, and of particular significance here, the PBM Defendants contract with pharmaceutical manufacturers, including the Manufacturer Defendants. The PBMs extract from the Manufacturers rebates, fees, and other consideration that are paid back to the PBMs, including the Manufacturer Payments related to the at-issue drugs.

267. The Manufacturers also interact with the PBMs related to other services outside the scope of the Insulin Pricing Scheme, such as health and educational programs and patient and prescriber outreach with respect to drugs not at issue here.

268. These relationships allow PBMs to exert tremendous influence over what drugs are available throughout the United States, including in Cocke County, on what terms, and at what prices.

269. Thus, PBMs are at the center of the flow of pharmaceutical money. Historically and today PBMs:

- negotiate the price that payors pay for prescription drugs (based on prices generated by the Insulin Pricing Scheme);

- separately negotiate a different (and often lower) price that pharmacies in their networks receive for the same drug;
- set the amount in fees that the pharmacy pays back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme);
- set the price paid for each drug sold through their mail-order pharmacies (based on prices generated by the Insulin Pricing Scheme); and
- negotiate the amount that the Manufacturers pay back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme).

270. Yet, for most of these transactions, only the PBMs are privy to the amount that any other entity in this supply chain is paying or receiving for the same drugs. The contracts between the PBMs and Manufacturers are undisclosed to Plaintiff. Payors, including Plaintiff, do not know and cannot learn the terms of those contracts.

271. This lack of transparency affords Defendants the opportunity to extract billions of dollars from this payment and supply chain without detection.

272. In every interaction that the PBMs have within the pharmaceutical pricing chain, they stand to profit from the prices generated by the Insulin Pricing Scheme.

The Rise of the PBMs in the Pharmaceutical Supply Chain

273. At first, in the 1960s, pharmacy benefit managers functioned largely as claims processors. Over time, however, they have taken on increasingly larger roles.

274. One of the roles the pharmacy benefit managers have taken on, as discussed above, was negotiating with drug manufacturers—ostensibly on behalf of payors. In so doing, the PBMs affirmatively represented that they were using their leverage to drive down drug prices.

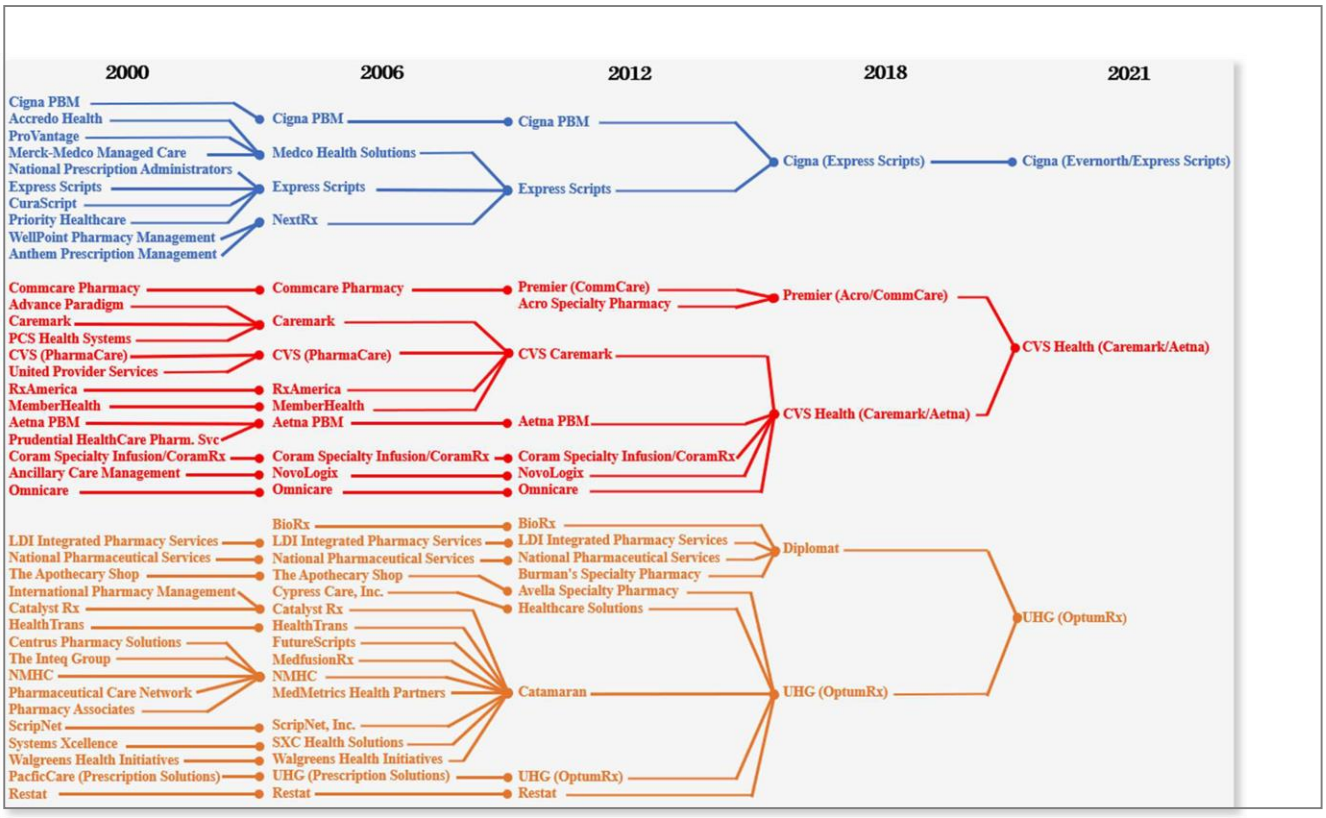
275. In the early 2000s, the PBMs started buying pharmacies, thus creating an additional incentive to collude with manufacturers to keep certain prices high.

276. These perverse incentives still exist today with respect to both retail and mail-order pharmacies housed within the PBMs' corporate families. Further recent consolidation in the industry has given the pharmacy benefit managers disproportionate market power.

277. Nearly forty pharmacy benefit manager entities have combined into what are now the three PBM Defendants. Moreover, each PBM Defendant now is owned by other significant players in the pharmaceutical chain, e.g., Express Scripts merged with Cigna; CVS bought Caremark, which now also owns Aetna; and UnitedHealth Group acquired OptumRx.

278. Figure 14 depicts this consolidation within the pharmacy benefit manager market.

Figure 14: PBM consolidation



279. After merging with or acquiring all of their competitors, and now backed by multibillion-dollar corporations, the PBM Defendants have taken over the market in the past

decade, controlling more than 80% of the market and managing pharmacy benefits for more than 270 million Americans.

280. Together, the PBM Defendants report more than $300 billion in annual revenue.

281. The PBMs use this market consolidation and the resulting purchasing power as leverage when negotiating with other entities in the pharmaceutical pricing chain.

The Insular Nature of the Pharmaceutical Industry

282. The insular nature of the pharmaceutical industry has provided Defendants with ample opportunity to contact and communicate with the other PBM and Manufacturer Defendants and to devise, coordinate, and carry out the Insulin Pricing Scheme.

283. The Manufacturer Defendants are all members of the industry-funded Pharmaceutical Research and Manufacturers of America ("PhRMA") and routinely communicate through PhRMA meetings and platforms in furtherance of the Insulin Pricing Scheme. According to PhRMA's 2019 IRS Form 990, it received $515,420,431 in "membership dues." All members are pharmaceutical companies.[29]

284. David Ricks (CEO of Eli Lilly), Paul Hudson (CEO of Sanofi), and Douglas Langa (President of Novo Nordisk and EVP of North American Operations), serve on the PhRMA board of directors and/or part of the PhRMA executive leadership team.

285. The PBM Defendants also routinely communicate through direct interaction with their competitors and the Manufacturers at trade associations and industry conferences.

[29] PhRMA 2019 Form 990, https://projects.propublica.org/nonprofits/organizations/530241211/202043189349300519/full; PhRMA, About PhRMA, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/About-PhRMA2.pdf (last visited Aug.23,2023).

286. Each year during the relevant period, the main PBM trade association, the industry-funded Pharmaceutical Care Management Association ("PCMA"), held several yearly conferences, including its Annual Meeting and its Business Forum conferences.[30]

287. The PCMA is governed by PBM executives. The current (July 2023) board of the PCMA includes David Joyner (Executive Vice President and President of Pharmacy Services of PBM Defendant CVS Caremark); Adam Kautzner (President of PBM Defendant Express Scripts); and Heather Cianfrocco (CEO of PBM Defendant OptumRx).

288. In 2022, Former Express Scripts President Amy Bricker was the Chair of the PCMA board of directors and the only Express Scripts employee on the board. But when Ms. Bricker left Express Scripts in late 2022/early 2023, she was removed from the PCMA board. On February 3, 2023, PCMA issued a press release naming Mr. Kautzner to the board and appointing him Chairman of the Board of Directors. Mr. Kautzner was not on the board as of late 2022. Mr. Kauztner was added to the PCMA board and named Chair of the board to ensure that the PCMA board has directors from all three PBM Defendants and to facilitate the Insulin Pricing Scheme.

289. All PBM Defendants are members of the PCMA and, due to their leadership positions, have substantial control over that association.

290. Additionally, the Manufacturer Defendants are affiliate members of the PCMA.

291. Every year, high-level representatives and corporate officers from both the PBM and Manufacturer Defendants attend these conferences to meet in person and engage in discussions, including those in furtherance of the Insulin Pricing Scheme.

[30] The PCMA's industry funding in the form of "membership dues" is set out in its 2019 Form 990, https://projects.propublica.org/nonprofits/organizations/383676760/202042969349301134/full (last visited Aug, 23, 2023).

292. In fact, for at least the last eight years, all Manufacturer Defendants have been "Partners," "Platinum Sponsors," or "Presidential Sponsors" of these PBM conferences.

293. Notably, many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications. For example, as Presidential Sponsors of these conferences, Manufacturer Defendants each hosted "private meeting rooms" that offer "excellent opportunities for . . . one-on-one interactions between PBM and pharma executives."[31]

294. Representatives from each Manufacturer Defendant have routinely met privately with representatives from each PBM Defendant during the Annual Meetings and Business Forum conferences that the PCMA holds (and the manufacturers sponsor) each year.

295. In addition, all PCMA members, affiliates and registered attendees of these conferences are invited to join PCMA-Connect, "invitation only LinkedIn group and online networking community."[32]

296. As PCMA members, the PBM and Manufacturer Defendants clearly utilized both PCMA-Connect, as well as the private meetings at the PCMA conferences, to exchange information and to reach agreements in furtherance of the Insulin Pricing Scheme.

297. Key at-issue lockstep price increases occurred shortly after the Defendants had convened at PCMA meetings. For example, on September 26 and 27, 2017, the PCMA held its annual meeting where each of the Manufacturer Defendants hosted private rooms and executives from each Defendant engaged in several meetings throughout the conference. Mere days after the

[31] PCMA, *The PCMA Annual Meeting 2021 Will Take Place at the Broadmoor in Colorado Springs, CO September 20 and 21*, https://www.pcmanet.org/pcmaevent/annual-meeting-2021/ (an event "tailored specifically for senior executives from PBMs and their affiliated business partners" with "private reception rooms" and "interactions between PBM members, drug manufacturers, and other industry partners") (last visited Aug 23, 2023).

[32] PCMA, *PCMA-Connect*, https://www.pcmanet.org/contact/pcma-connect/ (last visited Sept. 9, 2022).

conference, on October 1, 2017, Sanofi increased Lantus's list price by 3% and Toujeo's list by 5.4%. Novo Nordisk also recommended that their company make a 4% list price increase effective on January 1, 2018, to match the Sanofi increase.

298. Likewise, on May 30, 2014, Novo Nordisk raised the list price of Levemir a matter of hours after Sanofi made its list price increase on Lantus. These price hikes occurred just weeks after the 2014 PCMA spring conference in Washington, D.C., attended by representatives from all the PBM Defendants.

299. The PBMs control the PCMA and have exploited it to further their interests and to conceal the Insulin Pricing Scheme. The PCMA has brought numerous lawsuits and lobbying campaigns aimed at blocking drug-pricing transparency efforts, including recently suing the Department of Health and Human Services (HHS) to block the finalized HHS "rebate rule," which would eliminate anti-kickback safe harbors for Manufacturer Payments and instead offer them as direct-to-consumer discounts.

300. Notably, the PCMA's 2019 tax return reports more than a million dollars in revenue for "litigation support." Prior tax returns available at ProPublica reveal millions of dollars in revenue for "litigation support" (and tens of millions in revenue for "industry relations") year after year.[33]

301. Communications among the PBM Defendants are facilitated by the fluidity and frequency with which executives relocate from one PBM Defendant to another. For example:

- Mark Thierer worked as an executive at Caremark Rx (now CVS Caremark) prior to becoming the CEO of OptumRx in 2016 (he also served as Chairman of the Board for PCMA starting in 2012);

- Bill Wolfe was the President of the PBM Catalyst Rx (now OptumRx) prior to becoming the President of Aetna Rx in 2015 (he also served as a PCMA board member from 2015-2017 while with Aetna Rx);

[33] *See, e.g.*, PCMA 2019 Form 990, *supra* note 24, and prior years' returns on ProPublica.

- Derica Rice, former EVP for CVS Health and President of CVS Caremark, previously served as EVP and CFO for Eli Lilly;

- Duane Barnes was the Vice President of Medco (now Express Scripts) before becoming division President of Aetna Rx in 2006 (he also served as a PCMA board member);

- Everett Neville was the division President of Aetna Rx before becoming Senior Vice President of Express Scripts;

- Albert Thigpen was a Senior Vice President at CVS Caremark for 11 years before becoming a Senior Vice President at OptumRx in 2011;

- Harry Travis was the Chief Operating Officer at Medco (now Express Scripts) before becoming a Vice President at Aetna Rx in 2008; he served as SVP Member Services Operations for CVS Caremark from 2020-2022; and

- Bill Kiefer was a Vice President of Express Scripts for 14 years before becoming Senior Vice President of Strategy at OptumRx in 2013.

E. The Insulin Pricing Scheme

302. The market for the at-issue diabetes medications is unique in that it is highly concentrated with no true generics and few biosimilar options. The drugs and biosimilars have similar efficacy and risk profiles.

303. This affords the PBMs great leverage that, in theory, could be used to negotiate with the Manufacturer Defendants to drive down list prices for the at-issue drugs through open competition.

304. But the PBMs do not want the prices for diabetes medications to go down. A 2022 report by the Community Oncology Alliance put it this way:

> Among the different sources of revenue, the most prolific by far is in the form of rebates from pharmaceutical manufacturers that PBMs extract in exchange for placing the manufacturer's product drug on a plan sponsor's formulary or encouraging utilization of the manufacturer's drugs . . . . [T]he growing number and scale of rebates is the primary fuel of today's high drug prices. The truth is that PBMs have a vested interest to have drug prices remain high, and to extract rebates

> off of these higher prices. PBM formularies tend to favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates.[34]

305. The Manufacturer Defendants understand that PBM Defendants make more money as prices increase. This is confirmed by the January 2021 Senate Insulin Report after review of internal documents produced by the Manufacturers: [B]oth Eli Lilly and Novo Nordisk executives, when considering lower list prices, were sensitive to the fact that PBMs largely make their money on rebates and fees that are based on a percentage of a drug's list price.[35]

306. The documents eventually released by the Senate also show how the Manufacturers' pricing strategy focuses on *the PBMs' profitability*. In an internal August 6, 2015, email, Novo Nordisk executives debated delaying increasing the price of an at-issue drug in order to make the increase more profitable for *CVS Caremark*, stating:

> Should we take 8/18 [for a price increase], as agreed to by our [pricing committee], or do we recommend pushing back due to the recent CVS concerns on how we take price? . . . We know CVS has stated their disappointment with our price increase strategy (ie taking just after the 45th day) and how it essentially results in a lower price protection, admin fee and rebate payment for that quarter/time after our increase . . . it has been costing CVS a good amount of money. [36]

307. The Manufacturer Defendants also understand that because of the PBMs' market dominance, most payors, including Plaintiff Cocke County and its Beneficiaries, accept the baseline national formularies offered by the PBMs with respect to the at-issue drugs.

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[34] Community Oncology Alliance & Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers* (Feb. 2022), https://communityoncology.org/wpcontent/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf (last visited Jan. 14, 2023).

[35] Grassley & Wyden, *supra* note 2 at 89.

[36] Letter from Raphael A. Prober, Counsel for Novo Nordisk Inc., to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Novo_ Redacted.pdf (last visited Jan. 15, 2023).

308. The Insulin Pricing Scheme was borne from these understandings. Both sets of Defendants realized that if the Manufacturers artificially inflate their list prices while paying large, undisclosed Manufacturer Payments back to the PBMs, both the PBMs and Manufacturers would generate billions of unearned dollars. The plan worked.

309. Over the past several years the Manufacturers have raised prices in unison and have paid correspondingly larger Manufacturer Payments to the PBMs.

310. In exchange for the Manufacturers artificially inflating their prices and paying the PBMs substantial amounts in Manufacturer Payments, the PBM Defendants grant the Manufacturer Defendants' diabetes medications elevated prices and preferred status on their national formularies. During the relevant period, the rebate amounts (as a proportion of the list price) grew year-over-year while list prices themselves increased.

311. Beyond increased rebate demands, the PBMs also have sought and received larger and larger administrative fee payments and other Manufacturer Payments from the Manufacturers during the relevant period.

312. A recent study by the Pew Charitable Trust estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs requested and received from the Manufacturers tripled, reaching more than $16 billion. The study observed that, although rebates were sent to payors during this period, PBMs retained the same volume of rebates in pure dollars, given the overall growth in rebate volume while administrative fees and spread pricing (charging a client payor more for a drug than the PBM pays the pharmacy) further offset reductions in retained rebate volumes.

313. Thus—and contrary to their public representations—the PBM Defendants' negotiations and agreements with the Manufacturer Defendants (and the formularies that result

from these agreements) have caused and continue to cause precipitous price increases for the at-issue drugs.

314. As a result of the Insulin Pricing Scheme, every payor, including Plaintiff, that pays for and/or reimburses for the at-issue drugs has been overcharged.

315. Moreover, the PBMs use this false price to misrepresent the amount of "savings" they generate for diabetics, payors, and the healthcare system. For example, in January 2016, Express Scripts' president Tim Wentworth stated at the 34th annual JP Morgan Healthcare Conference that Express Scripts "saved our clients more than $3 billion through the Express Scripts National Preferred Formulary."[37] Likewise, in April 2019, CVS Caremark President Derica Rice stated: "Over the last three years . . . CVS Caremark has helped our clients save more than $141 billion by blunting drug price inflation, prioritizing the use of effective, lower-cost drugs and reducing the member's out-of-pocket spend."[38]

316. In making these representations, the PBMs fail to disclose that the amount of "savings" generated is calculated based on the false list price, which is not paid by any entity in the pharmaceutical pricing chain and which all Defendants are directly responsible for artificially inflating.

317. The Insulin Pricing Scheme is a coordinated effort among the Manufacturer and PBM Defendants in which each agreed to, and did, participate, and which created enormous profits for all. For example:

a. The Manufacturers and the PBMs are in constant communication and regularly meet and exchange information to construct and refine the PBM formularies that

[37] Surabhi Dangi-Garimella, *PBMs Can Help Bend the Cost Curve: Express Scripts' Tim Wentworth*, AJMC (Jan. 12, 2016), https://www.ajmc.com/view/pbms-can-help-bendthe-cost-curve-express-scripts-tim-wentworth (last visited Jan. 15, 2023).

[38] CVS Health, *CVS Health PBM Solutions Blunted the Impact of Drug Price Inflation, Helped Reduce Member Cost, and Improved Medication Adherence in 2018* (Apr. 11, 2019), https://www.cvshealth.com/news-and-insights/press-releases/cvs-health-pbmsolutions-blunted-the-impact-of-drug-price (last visited Jan. 11, 2023).

form and fuel the scheme. As part of these communications, the Manufacturers are directly involved in determining not only where their own diabetes medications are placed on the PBMs' formularies and with what restrictions, but also in determining the same for competing products;

b. The Manufacturers and the PBMs share confidential and proprietary information with each other in furtherance of the Insulin Pricing Scheme, such as market data gleaned from the PBMs' drug utilization tracking efforts and mail-order pharmacy claims, internal medical efficacy studies, and financial data. Defendants then use this information in coordination to set the false prices for the at-issue medications and to construct their formularies in the manner that is most profitable for both sets of Defendants. The data that is used to further this coordinated scheme is compiled, analyzed, and shared either by departments directly housed within the PBM or by subsidiaries of the PBM, as is the case with OptumRx, which utilizes OptumInsight and Optum Analytics; and

c. The Manufacturers and the PBMs engage in coordinated outreach programs directly to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters in tandem to send out to diabetes patients on behalf of the PBMs' clients. For example, the Grassley-Wyden Senate committee recently released an email where Eli Lilly discussed paying Defendant UnitedHealth Group and OptumRx additional rebates for every client that was converted to formularies that exclusively preferred Eli Lilly's at-issue drugs, including Humalog. The email continued: "United's leadership committee made one ask of Lilly – that we are highly engaged in the communication/pull through plan.[39] I of course indicated we fully expect to support this massive patient transition [to Eli Lilly's at-issue drugs favored by United] and provider education with the full breadth of Lilly resources. UHC also proactively thanked Lilly for our responsiveness, solution generation and DBU execution."

318. Rather than using their prodigious bargaining power to lower drug prices as they claim, Defendants instead used their dominant positions to conspire to generate billions of dollars in illicit profits at the expense of payors like Plaintiff.

F. Defendants Play Down the Insulin Pricing Scheme and Its Harms

319. On April 10, 2019, the United States House of Representatives Committee on Energy and Commerce held a hearing on industry practices titled, "Priced Out of a Lifesaving

[39] "Pull through" is an industry term that refers to an integrated process between PBMs and Manufacturers aimed at moving market share and increasing sales for a certain product following the PBM granting that product preferred placement on its formulary.

Drug: Getting Answers on the Rising Cost of Insulin."[40]

320. Representatives from all Defendants testified at the hearing, and each acknowledged before Congress that the price for insulin has increased exponentially in the past 15 years.

321. Further, each Defendant conceded that the price that diabetics pay out-of-pocket for insulin is too high. For example:

- Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx since 2015, stated: "A lack of meaningful competition allows the [M]anufacturers to set high [list] prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades. These price increases have a real impact on consumers in the form of higher out-of-pocket costs."

- Thomas Moriarty, Chief Policy and External Affairs Officer and General Counsel for CVS Health testified: "A real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, [list] prices for insulin have increased nearly 50 percent. And over the last ten years, [list] price of one product, Lantus, rose by 184 percent."

- Mike Mason, Senior Vice President of Eli Lilly when discussing how much diabetics pay out-of-pocket for insulin stated: "it's difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don't have affordable access to chronic medications . . ."

- Kathleen Tregoning, Executive Vice President External Affairs at Sanofi, testified: "Patients are rightfully angry about rising out-of-pocket costs and we all have a responsibility to address a system that is clearly failing too many people. . . we recognize the need to address the very real challenges of affordability . . . Since 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients . . ."

- Doug Langa, Executive Vice President of Novo Nordisk, stated: "On the issue of affordability . . . I will tell you that at Novo Nordisk we are accountable for the [list] prices of our medicines. We also know that [list] price matters to many, particularly those in high-deductible health plans and those that are uninsured."

[40] https:// www.congress.gov/event/116th-congress/house-event/109299?s=1&r=3 (last visited Jan. 9, 2023) (hereinafter *Priced Out of a Lifesaving Drug*).

322. None of the testifying Defendants claimed that the significant increase in the price of insulin was related to competitive factors such as increased production costs or improved clinical benefit.

323. Instead, Novo Nordisk's President Doug Langa's written testimony for the April 2019 hearing recognized "misaligned incentives" that have led to higher drug costs, including for insulin: "Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC [list] price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others." Likewise, Mr. Langa's responses to questions for the record conceded that "[t]he disadvantage of a system in which administrative fees are paid as a percentage of the list price is that there is increased pressure to keep list prices high. . . ." The hearing transcript records Mr. Langa's further comments in this regard:

> So as you heard from Dr. Cefalu last week of the ADA [American Diabetes Association], there is this perverse incentive and misaligned incentives and this encouragement to keep list prices high. And *we've been participating in that system* because the higher the list price, the higher the rebate . . . There is a significant demand for rebates…. *We're spending almost $18 billion a year in rebates*, discount, and fees, and *we have people with insurance with diabetes that don't get the benefit of that*. (emphasis added)

324. Eli Lilly admitted that it raises list prices as a quid pro quo for formulary positions. At the April 2019 Congressional hearing, Mike Mason, Senior Vice President of Eli Lilly, testified:

> Seventy-five percent of our list price is paid for rebates and discounts . . . . $210 of a vial of Humalog is paid for discounts and rebates. . . . We have to provide rebates [to PBMs] in order to provide and compete for that [formulary position] so that people can use our insulin. In the very next question, Mr. Langa of Novo Nordisk was asked, "[H]ave you ever lowered a list price? His answer: "We have not."

325. Sanofi's Executive Vice President for External Affairs, Kathleen Tregoning, testified:

> The rebates is [sic] how the system has evolved. . . . I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient.

Her written response to questions for the record acknowledged that "it is clear that payments based on a percentage of list price result in a higher margin [for PBMs] for the higher list price product than for the lower list price product."

326. The PBM Defendants also conceded at the April 2019 Congressional hearing that they grant preferred, or even exclusive, formulary position because of higher Manufacturer Payments paid by the Manufacturer Defendants.

327. In her responses to questions for the record, Amy Bricker, former SVP of Express Scripts and PCMA board member, confirmed that "manufacturers lowering their list prices" would give patients "greater access to medications;" yet when asked to explain why Express Scripts did not grant an insulin with a lower list price preferred formulary status, answered, "Manufacturers do give higher discounts [i.e., payments] for exclusive [formulary] position . . ." When asked why the PBM would not include both costly and lower-priced insulin medications on its formulary, Ms. Bricker stated plainly, "We'll receive less discount in the event we do that."[41]

328. As Dr. Dutta, SVP of OptumRx, perversely reasoned, the cheaper list-priced alternative Admelog is not given preference on the formulary because "it would cost the payer more money to do that . . . because the list price is not what the payer is paying. They are paying

[41] Buried in Express Scripts' 2017 10-K is the following: "We maintain contractual relationships with numerous pharmaceutical manufacturers, which provide us with, among other things administrative fees for managing rebate programs, including the development and maintenance of formularies that include particular manufacturer's products . . . ." That is, the Manufacturers pay the PBMs to effectively participate in the creation of formularies that payors are required to adopt as a condition for obtaining PBM services. Express Scripts Annual Report (Form 10-K) (FYE Dec. 31, 2017) at 24. It also notes that its business would be "adversely affected" if it were to "lose [its] relationship with one or more key pharmaceutical manufacturers." *Id.*

the net price."[42] In other words, under the pricing scheme, PBMs and manufacturers can make a drug with a lower list price effectively more expensive for payors and then ostensibly save payors from that artificially inflated price by giving preference to drugs that had higher list prices to begin with (yielding higher Manufacturer Payments to the PBMs).

329. While all Defendants acknowledged before Congress their participation in conduct integral to the Insulin Pricing Scheme, none revealed its inner workings or the connection between their coordination and the economic harm that payors, like Plaintiff, and Beneficiaries were unwittingly suffering. Instead, in an effort to obscure the true reason for precipitous price increases, each Defendant group pointed the finger at the other as the more responsible party.

330. The PBM Defendants testified to Congress that the Manufacturer Defendants are solely responsible for their list price increases and that the Manufacturer Payments that the PBMs receive are not correlated to rising insulin prices.

331. This testimony is false. The amounts Manufacturers pay back to the PBMs is *directly correlated* to an increase in list prices. On average, a $1 increase in Manufacturer Payments is associated with a $1.17 increase in list price. Reducing or eliminating Manufacturer Payments would lower prices and reduce out-of-pocket expenditures.

332. Further, in large part because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown substantially over the same time period that insulin prices have steadily increased. For example, since 2003, Defendant Express Scripts has seen its profit per prescription increase more than 500% per adjusted prescription.[43]

[42] *Id.* As noted in the hearing, even the "cheaper" alternative Admelog "costs over $200 a bottle."

[43] David Balto, *How PBMs Make the Drug Price Problem Worse*, Hill (Aug. 31, 2016, 5:51 PM), https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-thedrug-price-problem-worse (last visited Jan. 15, 2023).

333. Novo Nordisk's President, Doug Langa, submitted written testimony to Congress acknowledging "there is no doubt that the WAC [list price] is a significant component" of "what patients ultimately pay at the pharmacy counter." Yet, the Manufacturers urged upon Congress the fiction that the PBMs were solely to blame for insulin prices because of their demands for rebates in exchange for formulary placement. The Manufacturers claimed their hands were tied and sought to conceal their misconduct by suggesting that they have not profited off rising insulin prices.

334. Given the Manufacturers' claims that rebates were the sole reason for rising prices, each was asked directly during the Congressional hearing to guarantee it would decrease list prices if rebates were restricted or eliminated. The spokespersons for Eli Lilly, Novo Nordisk and Sanofi all said only that they would "consider it."

335. In addition, a 2020 study from the Institute of New Economic Thinking titled, "Profits, Innovation and Financialization in the Insulin Industry," demonstrates that during the time insulin price increases were at their steepest, distributions to the Manufacturers' shareholders in the form of cash dividends and share repurchases totaled $122 billion. In fact, during this period the Manufacturers spent a significantly lower proportion of profits on R&D compared to shareholder payouts. The paper also notes that "[t]he mean price paid by patients for insulin in the United States almost tripled between 2002 and 2013" and that "per-person spending on insulin by patients and insurance plans in the United States doubled between 2012 and 2016, despite only a marginal increase in insulin use."[44]

336. The 2022 Community Oncology Alliance report found:[45]

[44] Rosie Collington, *Profits, Innovation and Financialization in the Insulin Industry*, Inst. for New Econ. Thinking (Apr. 2020), https://www.ineteconomics.org/research/research-papers/ profits-innovation-and-financialization-in-the-insulin-industry (last visited Jan. 15, 2023).

[45] Community Oncology Alliance, *supra* note 29.

> [T]here are several important ways that PBM rebates increase the costs of drugs for both plan sponsors and patients. . . . PBMs employ exceedingly vague and ambiguous contractual terms to recast monies received from manufacturers outside the traditional definition of rebates, which in most cases must be shared with plan sponsors. Rebate administration fees, *bona fide* service fees, and specialty pharmacy discounts/fees are all forms of money received by PBMs and rebate aggregators which may not be shared with (or even disclosed to) the plan sponsor. These charges serve to increase the overall costs of drugs, while providing no benefit whatsoever to plan sponsors. . . . The total drug spend of a plan sponsor, regardless of whether it is a federal or state governmental program or a self-funded employer, will inevitably increase because PBMs are incentivized to favor expensive drugs that yield high rebates. . . .

337. In January 2021, the Senate Finance Committee (Grassley-Wyden) issued a report titled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,"[46] which detailed Congress's findings after reviewing more than 100,000 pages of internal company documents from Sanofi, Novo Nordisk, Eli Lilly, CVS Caremark, Express Scripts, OptumRx, and Cigna. The report concluded, among other things:

- The Manufacturer Defendants retain more revenue from insulin than in the 2000s—for example, Eli Lilly has reported a steady increase in Humalog revenue for more than a decade—from $1.5 billion in 2007 to $3 billion in 2018;
- The Manufacturer Defendants have aggressively raised the list price of their Insulin products absent significant advances in the efficacy of the drugs; and
- The Manufacturer Defendants only spend a fraction of their revenue related to the at-issue drugs on research and development—Eli Lilly spent $395 million on R&D costs for Humalog, Humulin, and Basaglar between 2014-2018, during which time the company generated $22.4 billion in revenue on these drugs.

[46] Grassley & Wyden, *supra* note 2 at 5, 7.

338. The truth is that, despite their finger pointing in front of Congress, the Manufacturers and PBMs are *both* responsible for their concerted efforts in creating the Insulin Pricing Scheme.

G. Defendants Profit from the Insulin Pricing Scheme

339. The Insulin Pricing Scheme affords the Manufacturer Defendants the ability to pay the PBM Defendants secret but significant Manufacturer Payments in exchange for formulary placement, which garners the Manufacturer Defendants greater revenues from sales without decreasing their profit margins. During the relevant period, the PBM Defendants granted national formulary position to each at-issue drug in exchange for large Manufacturer Payments and inflated prices.

340. The Manufacturer Defendants also use the inflated price to earn hundreds of millions of dollars in additional tax breaks by basing their deductions for donated insulins on the inflated list price.

341. Because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown exponentially during the relevant period as well. A recent study published in the Journal of the American Medical Association concluded that the amount of money that goes to the PBM Defendants for each insulin prescription increased more than 150% from 2014 to 2018. In fact, for transactions where the PBM Defendants control the PBM and the pharmacy (e.g., Caremark-CVS pharmacy) these Defendants were capturing an astonishing 40% of the money spent on each insulin prescription (up from only 25% just four years earlier), despite the fact that they do not contribute to the development, manufacture, innovation or production of the product.[47]

[47] Karen Van Nuys, et al., *Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018*,

342. The PBM Defendants profit from the artificially inflated prices created by the Insulin Pricing Scheme in a number of ways, including by: (1) retaining a significant, yet undisclosed, percentage of the Manufacturers Payments, (2) using the inflated list price to generate profits from pharmacies, and (3) relying on the inflated list price to drive up the PBMs' margins through their own mail-order pharmacies.

The PBMs Pocket a Substantial Share of Manufacturer Payments

343. The first way in which the PBMs profit from the Insulin Pricing Scheme is by keeping a significant portion of the secret Manufacturer Payments.

344. The amount that the Manufacturers pay back to the PBMs has increased over time both in real dollars and as a proportion of the ever-increasing list prices.

345. Historically, contracts between PBMs and payors allowed the PBMs to keep most or all of the rebates they received, rather than forwarding them to the payor.

346. Over time, payors secured contract provisions guaranteeing payment to them of all or some portion of the rebates paid by the Manufacturers to the PBMs. Critically, however, "rebates" are only one aspect of the total Manufacturer Payments, particularly as "rebates" are narrowly defined and qualified by vague exceptions in the PBM contracts with payors.

347. Indeed, as described in the January 2021 Senate Insulin Report, the PBMs and Manufacturers coordinate to determine the contract options made available to payors: "Contracts between PBMs and manufacturers provide a menu of options from which their health plan clients can choose certain terms and conditions."[48] The contracts between the PBMs and Manufacturers also "stipulate terms the plans must follow regarding factors such as formulary placement and

JAMA Network (Nov. 5, 2021), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932 (last visited Aug. 23, 2023).

[48] Grassley & Wyden, *supra* note 2 at 40.

competition from other drugs in the therapeutic class."[49] Thus, the Manufacturers ultimately played a role in dictating the terms and conditions of the contracts that payors like Plaintiff entered into with PBMs. Of course, the payors were not involved in the coordination or the negotiation of the contracts between the PBMs and Manufacturers and the PBMs disclosed only the fact that such relationships may exist—the terms of the contracts, the consideration exchanged between the PBMs and Manufacturers, and the means of reaching these determinations all were and remain shrouded in secrecy.

348. The PBM and Manufacturer Defendants thus created a "hide-the-ball" system where payors like Plaintiff are not privy to rebate negotiations or contracts between the Manufacturers and the PBMs. The consideration exchanged between them (and not shared with payors) is labeled and relabeled. As more payors moved to contracts that required PBMs to remit some or all of the manufacturer "rebates" through to the payor, the PBMs rechristened Manufacturer Payments to shield them from scrutiny and from their payment obligations. Payments once called "rebates" now include administrative fees, volume discounts, service fees, inflation fees, or other industry monikers designed to obfuscate the substantial sums being secretly exchanged between the PBMs and the Manufacturers.

349. Just last year, the Senate Commerce, Science and Transportation Committee released testimony from David Balto—a former antitrust attorney with the DOJ and Policy Director for the FTC's Bureau of Competition—from a hearing on fairness and transparency in drug pricing:

> The PBM rebate system turns competition on its head with PBMs seeking higher, not lower prices to maximize rebates and profits. In the past decade, PBM profits have increased to $28 billion annually. . . . PBMs establish tremendous roadblocks to prevent payors from knowing the amount of rebates they secure. Even sophisticated buyers are unable to secure specific drug by drug rebate information.

[49] *Id.* at 44.

> PBMs prevent payors from being able to audit rebate information. As the Council of Economic Advisors observed, the PBM market lacks transparency as "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret." Without adequate transparency, plan sponsors cannot determine if the PBMs are fully passing on any savings, or whether their formulary choices really benefit the plan and subscribers.

350. The renamed, undisclosed Manufacturer Payments are substantial. "Administrative fees" are one example. A heavily redacted complaint filed by Defendant Express Scripts in 2017 revealed that Express Scripts retains up to 13 times more in "administrative fees" than it remits to payors in rebates.[50]

351. These so-called administrative fees typically are based on a percentage of the drug price—as opposed to a flat fee—such that even if the actual "administrative" cost associated with processing two drugs is the same, the "administrative fee" would be correspondingly higher for the higher-priced drug, which creates (by design) a perverse incentive to give preference to more expensive drugs. Moreover, the PBM Defendants' contracts with payors, including those with Plaintiff, narrowly define "rebates" by tying them to patient drug utilization, so rebates for formulary placement are characterized as "administrative fees" that are not remitted to payors and are beyond a payor's contractual audit right to verify the accuracy of "rebate" payments under the contracts.

352. The opaque nature of these arrangements between the Manufacturers and PBM Defendants also makes it impossible for a given payor to discover, much less assess or confront, conflicts of interest that may affect it or its members. The January 2021 Senate Insulin Report observed with respect to these arrangements: "Relatively little is publicly known about these financial relationships and the impact they have on insulin costs borne by consumers."[51]

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[50] *Express Scripts, Inc. v. Kaleo, Inc.*, No. 4:17-cv-01520-RLW (E.D. Mo. 2017).
[51] Grassley & Wyden, *supra* note 2 at 4.

353. Unsurprisingly, the PBMs have gone to great lengths to obscure these renamed Manufacturer Payments in order keep them for themselves and to avoid scrutiny from payors and others.

354. For example, with regard to the Manufacturer Payments now known as "inflation fees," the PBMs often create a hidden gap between how much the Manufacturers pay them to increase their prices and the amount in "price protection guarantees" that the PBMs agree to pay back to their client payors.

355. In particular, the Manufacturer Defendants often pay the PBM Defendants "inflation fees" in order to increase the price of their diabetes medications. The thresholds for these payments are typically set at around 6% to 8%—if the Manufacturer Defendants raise their prices by more than the set percentage during a specified time period, they pay the PBM Defendants an additional "inflation fee" (based on a percentage of the list prices).

356. For many of their clients, the PBMs have separate "price protection guarantees" that state that if the overall drug prices for that payor increase by more than a set amount, then the PBMs will remit a portion of the amount to the client.

357. The PBMs set these "price protection guarantees" at a higher rate than the thresholds that trigger the Manufacturers' "inflation fees," usually around 10%-15%.

358. Thus, if the Manufacturers increase their list prices more than the 6% (or 8%) inflation fee rate but less than the 10%-15% client price protection guarantee rate, then the PBMs keep all of these "inflation fee" payments. This is a win-win for the Manufacturers and PBMs—they share and retain the entire benefit of these price increases while the PBM contracts with payors imply that payors are protected from price hikes by their price protection guarantees.

359. The PBMs also hide the renamed Manufacturer Payments with "rebate aggregators." Rebate aggregators, sometimes referred to as rebate group purchasing organizations ("GPOs"), are entities that negotiate for and collect payments from drug manufacturers, including the Manufacturer Defendants, on behalf of a large group of pharmacy benefit managers (including the PBM Defendants) and different entities that contract for pharmaceutical drugs.

360. These rebate aggregators are often affiliated with or owned by the PBM Defendants, such as Ascent Health Services (Express Scripts), Coalition for Advanced Pharmacy Services and Emisar Pharma Services (OptumRx), and Zinc (CVS Caremark).

361. The PBMs carefully guard the revenue streams from their rebate aggregator activities, hiding them in complex contractual relationships and not reporting them separately in their quarterly SEC filings.

362. Certain rebate-aggregator companies are located offshore, for example, in Switzerland (Express Scripts' Ascent Health) and Ireland (Emisar Pharma Services), making oversight even more difficult.

363. As summarized by the recent Community Oncology Alliance report:[52]

> PBMs have increasingly "delegated" the collection of manufacturer rebates to "rebate aggregators," which are often owned by or affiliated with the PBMs, without seeking authorization from plan sponsors and without telling plan sponsors. . . . Even some of the major PBMs (i.e., the "Big Three" PBMs) sometimes find themselves contracting with other PBMs' rebate aggregators for the collection of manufacturer rebates. . . . In both the private sector and with respect to government health care programs, the contracts regarding manufacturer rebates (i.e., contracts between PBMs and rebate aggregators, as well as contracts between PBMs/rebate aggregators and pharmaceutical manufacturers) are not readily available to plan sponsors.

364. For example, a 2017 audit conducted by a local governmental entity on Defendant OptumRx related to its PBM activities from 2013 to 2015 concluded that the auditor was unable

[52] Community Oncology Alliance, *supra* note 29.

to verify the percentage of rebates OptumRx remitted to its client payor because OptumRx would not allow the auditor access to its rebate contracts. The audit report explained:

> Optum[Rx] has stated that it engaged the services of an aggregator to manage its rebate activity. Optum[Rx] shared that under this model, they are paid by their aggregator a certain amount per prescription referred. Then, the aggregator, through another entity, seeks rebates from the drug manufacturers, based upon the referred [Payor Client] prescription utilization, and retains any rebate amounts that may be received. Optum[Rx] states that they have paid [Payor Client] all amounts it has received from its aggregator, and that they do not have access to the contracts between the aggregator (and its contractors) and the manufacturer. However, our understanding is that Optum[Rx] has an affiliate relationship with its aggregator.[53]

365. A footnote in the audit report clarifies that "Optum[Rx] contracted with Coalition for Advanced Pharmacy Services (CAPS), and CAPS in turn contracted with Express Scripts, Inc."

366. In other words, according to this report, OptumRx contracts with its own affiliate aggregator Coalition for Advanced Pharmacy Services, who then contracts with OptumRx's co-conspirator Express Scripts, who then contracts with the Manufacturers for rebates related to OptumRx's client's drug utilization. OptumRx then uses this complex relationship to obscure the amount of Manufacturer Payments that are being generated from its client's utilization.

367. A subsequent audit by the same local entity—covering the period September 2017 to September 2018, concluded:[54]

> Several material weaknesses in Broward's agreement with Optum were identified, many of which are commonplace across pharmacy benefit manager agreements in general. Due to contract weaknesses, comparison of Broward's PBM agreement, including rebate amounts received, to the Consultant's marketplace data is not feasible. Broward could save an estimated $1,480,000 per year in net prescription drug benefit expenses (based upon minimum rebate guarantees) by switching from

[53] Laura Rogers & Stacey Thomas, Broward County Florida, Audit of Pharmacy Benefit Management Services Agreement, No. 18-13 (Dec. 7, 2017), https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf (last visited Jan. 15, 2023).

[54] Broward County, Florida, *Analysis of Broward County's Prescription Drug Coverage*, https://www.broward.org/Auditor/Reports/Reports/082019_Exh1_BCRxDrug_19-15.pdf (last visited Aug. 23, 2023).

> its current flawed agreement with Optum, to an agreement with its Coalition, which offers clearly defined terms, increased rebate guarantees and cost saving requirements.

Among other "loopholes" discovered in the contract were a number of "flawed" (i.e., vague and manipulable) definitions—including the definition of Rebates, which "allows the exclusion of monies that should be included—and limitation with respect to "Pass Through Transparency Pricing."

368. The January 2021 Grassley-Wyden Senate Report summarizing findings of their two-year probe into the Insulin Pricing Scheme contained the following observation on these rebate aggregators[55]:

> [T]he recent partnership between Express Scripts and Prime Therapeutics may serve as a vehicle to avoid increasing legislative and regulatory scrutiny related to administrative fees by channeling such fees through a Swiss based group purchasing organization (GPO), Ascent Health. While there are several regulatory and legislative efforts underway to prohibit manufacturers from paying administrative fees to PBMs, there is no such effort to change the GPO safe harbor rules. New arrangements used by PBMs to collect fees should be an area of continued investigative interest for Congress.

369. Federal regulations governing Medicare attempt to capture all possible forms of Direct or Indirect Remuneration (DIR) to PBMs (and plan sponsors), defining DIR as "any form of price concession" received by a plan sponsor or PBM "from any source," including "discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. DIR also includes price concessions from and additional contingent payments to network pharmacies that cannot reasonably be determined at the point of sale."[56]

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[55] Grassley & Wyden, *supra* note 2 at 83.

[56] CMS, *Final Medicare Part D DIR Reporting Guidance for 2021* at 7, https://www.cms.gov/files/document/final2021dirreportingreqsmemo508v3.pdf (last visited Jan. 15, 2023).

370. The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) considers all of the following as DIR: rebates, grants, reduced price administrative services, PBM-retained rebates, PBM rebate guarantee amounts, all post-point of sale payments by pharmacies that are not included in the negotiating price including dispensing incentive payments, prompt pay discounts, and payment adjustments. On the other hand, "bona fide service fees from pharmaceutical manufacturers" and "remuneration for administrative services with no impact on the sponsor's or PBM's drug cost (e.g., PBM incentive payments)" are not considered DIR, but only to the extent they reflect fair market value for services rendered.[57]

371. Because the PBMs retain and conceal a majority of the secret Manufacturer Payments that they receive, they are able to reap significant profits on the Insulin Pricing Scheme.

372. Even where payor clients receive a portion of the Manufacturer Payments from their PBM, those payors still are significantly overcharged as a direct result of the Insulin Pricing Scheme given the extent to which Defendants have deceptively and egregiously inflated the prices of the at-issue drugs.

The Insulin Pricing Scheme Allows the PBMs to Profit Off Pharmacies

373. A second way the PBM Defendants profit off the Insulin Pricing Scheme is by using the Manufacturers' inflated price to derive profit from the pharmacies with whom they contract, including those in Cocke County.

374. Each PBM Defendant decides which pharmacies are included in the PBM's network and how much it will reimburse these pharmacies for each drug dispensed.

375. The PBM Defendants, in coordination with the Manufacturers, directly reach out to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes

[57] *Id.* at 6-7.

medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters together to send to diabetes patients on behalf of the PBMs' clients [58]. The Defendants also petition these recipients to use the PBM Defendants' mail-order pharmacies and have succeeded in convincing patients, pharmacies, and prescribing physicians to do so.

376. The PBMs pocket the spread between the amount that the PBMs are paid by their clients for the at-issue drugs (which are based on the prices generated by the Insulin Pricing Scheme) and the amount the PBM reimburses the pharmacy (which often is less). In other words, the PBMs charge a client like Cocke County more for a drug than the PBM pays the pharmacy and pockets the difference.

377. A bipartisan bill introduced in the Senate in 2022 (the Pharmacy Benefit Manager Transparency Act—S. 4293)—would have, criminalized spread pricing, which the bill defined as "[c]harg[ing] a health plan or payer a different amount for a prescription drug's ingredient cost or dispensing fee than the amount the pharmacy benefit manager reimburses a pharmacy for the prescription drug's ingredient cost or dispensing fee where the pharmacy benefit manager retains the amount of any such difference." The bill has not yet been enacted.[59]

378. Not coincidentally, the PBMs' industry-funded trade association PCMA spent $7.8 million on federal lobbying in 2021 and more $6 million through the third quarter of 2022.[60]

379. The PBMs often disclose the concept of spread pricing to payors, but only in vague terms that require no accountability and are not subject to the payors' audit rights because the revenue is not defined as a "rebate" in the PBM contracts with payors.

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[58] See supra 326(c).

[59] https://www.govtrack.us/congress/bills/117/s4293 (last visited Jan. 10, 2023).

[60] https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2021&id=D000028342 (2021); https://www.opensecrets.org/federallobbying/clients/summary?cycle= 2022&id=D000028342 (2022) (last visited Jan. 10, 2023).

380. This spread pricing, like the secret Manufacturer Payment negotiation, happens behind closed doors. There is no transparency, no commitment from the PBM Defendants to account for the cost effectiveness of a drug, and no communication to either the payor or the pharmacy to let them know if they are getting a fair deal.

381. The higher the Manufacturers' list prices, the more money the PBMs make off this spread. At the same time, a Beneficiary's out-of-pocket co-pay or deductible cost often is more than if the client had simply paid cash outside of his or her plan. On top of this, the PBM contracts generally allow no rebates to payors where the Beneficiary is responsible for 100% of the drug cost, e.g., under his or her deductible.

382. The PBMs also use the Insulin Pricing Scheme to generate additional profits from pharmacies by charging the pharmacies post-purchase fees, including DIR (Direct or Indirect Remuneration) fees, based on the list prices—and again, the higher the list price for each diabetes medication sold, the more fees the PBMs generate—or by applying "retrospective" discounts. So, for example, a payor's (and member's co-pay or deductible) cost may be $100, but the price is discounted post-purchase (between the PBM and the (often self-owned) pharmacy) to $90 with the spread going to the PBM.

383. CMS addressed these and similar DIR issues in a proposed rule in 2017. While noting the growth of "pharmacy price concessions" that "are negotiated between pharmacies and their sponsors or PBMs," CMS nevertheless concluded:[61]

> When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in manufacturer rebates and pharmacy price concessions in recent

[61] Medicare Program; Contract Year 2019 Policy and Technical Changes, 82 Fed. Reg. 56336 (Nov. 29, 2017), https://www.govinfo.gov/content/pkg/FR-2017-11-28/pdf/2017-25068.pdf. Last visited Aug 23, 2023.

> years, the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price is rendered less transparent . . . .

CMS expressed further concern that when rebates and other price concessions are not reflected in the negotiated point-of-sale drug price, it "can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries . . . ."

384. PBMs thus make money coming and going. In a pre-PBM world, a competitively priced drug might have a (hypothetical) net cost to a health plan $50 and that is what it paid. PBMs enter the picture and coordinate with Manufacturers to increase the list price to $150. The PBMs then "negotiate" the inflated price down to $100 and take a $50 rebate, some of which may be forwarded to the payor, whose net cost is less than the inflated list price, but whose real-world cost is considerably more than if the PBMs were not involved.

385. At the same time, the PBM receives "administrative fees" for including certain drugs on its formularies, which are not considered "rebates." The PBM also receives "service fees" or other payment for "administrative services" provided to the Manufacturers such as "formulary compliance initiatives," "education services," or "the sale of non-patient identifiable claim information." All of these revenues are outside the definition of "rebates."

386. The PBM then charges payors like the County for administrative fees for providing pharmacy benefit management services and charges for drug costs (i.e. ingredient costs) and per-prescription dispensing fees, as well as additional administrative fees for services not included in the PBM's general administrative obligations. The PBM also receives rebates and/or discounts (pre-purchase or post-purchase) from the pharmacies, which it often owns. These too are excluded from the definition of "rebates." These and other vaguely described revenue streams are sometimes disclosed but only in hazy, overly generalized terms. And they are beyond a payor's contractual

rights to audit for "transparency" purposes because they are not defined "rebates." Additionally, the PBM may take months to pay rebates to payors and the PBM retains all interest on, and the time-value of, the rebates pending payment.

387. Payors have no access to, and no knowledge of, the intricacies of the dealings between the PBM Defendants and the Manufacturers that are shrouded by such vague "disclosures" (which vary in detail, but not in substance, in all three of the PBM Defendants' adhesive contracts).

The Insulin Pricing Scheme Increases PBM Mail-Order Profit

388. Another way PBMs profit from the Insulin Pricing Scheme is through the PBM Defendants' own mail-order pharmacies. The higher the price that PBM Defendants are able to get customers, such as Plaintiff, to pay for diabetes medications, the higher the profits PBM Defendants realize through their mail-order pharmacies.

389. Because the PBMs base the price they charge for the at-issue diabetes medications on the Manufacturers' price, the more the Manufacturers inflate their prices, the more money the PBMs make. For example, the PBMs have colluded with the Manufacturers so that the PBMs often know when the Manufacturers are going to raise their prices. The PBMs use this opportunity to purchase a significant amount of the at- issue drugs prior to the price increase, at the lower rate. Then, after the Manufacturers raise their price, the PBMs charge their mail-order customers based on the higher, increased prices and pocket the difference. The PBMs make significant amounts of money through this arbitrage scheme.

390. The PBMs also charge the Manufacturer Defendants fees related to their mail-order pharmacies, such as pharmacy supplemental discount fees, that are directly tied to the

Manufacturers' price. Thus, once again, the higher the price, the more money the PBMs make on these fees.

391. In sum, every way in which the PBMs make money on diabetes medications is tied directly to creating higher prices and inducing larger secret Manufacturer Payments. The PBMs are not lowering the price of diabetes medications as they publicly represent; they are making billions of dollars by fueling these skyrocketing prices.

H. Plaintiff Purchases the At-Issue Drugs Directly from Defendants

392. As a government employer, Plaintiff serves its residents by providing public safety, emergency management, and health services, among other vital roles. As more federal and state responsibilities are mandated to local government, Plaintiff has a growing list of demands on a limited budget. Consequently, any significant increase in spending can have a severe detrimental effect on Plaintiff's overall budget and, in turn, negatively impact its ability to provide necessary services to the community.

393. One benefit Plaintiff provides the Beneficiaries of its healthcare plan is payment for a large portion of their pharmaceutical purchases. In this role, Plaintiff spent significant amounts on the at-issue diabetes medications during the relevant period.

394. Because Plaintiff maintains a self-funded plan for County employees, Plaintiff does not rely on a third-party insurer to pay for insured employees' medical care, pharmaceutical benefits, or prescription drugs. Rather, Plaintiff directly contracts with, and directly pays, PBMs (and their affiliated pharmacies) for pharmaceutical benefits and prescription drugs, including the at-issue medications.

395. Plaintiff also purchased, and still purchases, the at-issue drugs directly from these PBMs (and their affiliated pharmacies) for use in Plaintiff's county-run facilities.

396. In the context of Plaintiff's purchases of the at-issue drugs, Plaintiff and its Beneficiaries are the only victims of the Insulin Pricing Scheme. Plaintiff is the only named party that pays the full purchase price for the at-issue drugs, and the only named party that has not knowingly participated in the Insulin Pricing Scheme. Neither the PBM Defendants nor the Manufacturers Defendants suffer losses from the Insulin Pricing Scheme.

397. As part of purchasing the at-issue drugs from the PBMs, Plaintiff directly pays the PBMs artificially inflated costs resulting from the Insulin Pricing Scheme, including "administrative fees," "inflation fees," "discount fees," and more—all of which are associated with Plaintiff's purchase of the at-issue drugs from the PBM Defendants. Because the at-issue medications are potentially life-saving drugs, and because the Manufacturers control the market for these drugs, Plaintiff has no choice but to pay these exorbitant, artificially inflated prices directly to PBM Defendants.

398. Plaintiff also relies (and has relied) on PBM Defendants as administrative agents, for the alleged purposes of limiting its administrative burden and controlling pharmaceutical drugs costs.

399. In providing PBM services to Plaintiff, including developing and offering formularies for Plaintiff's prescription plan, constructing and managing Plaintiff's pharmacy network (which included the PBMs' retail and mail-order pharmacies), processing pharmacy claims, and providing mail-order pharmacy services, PBM Defendants set the amount Plaintiff paid in coordination with the Manufacturer Defendants and, utilizing the false prices, generated by the Insulin Pricing Scheme. Plaintiff paid PBM Defendants directly for the at-issue drugs.

I. Defendants Deceived Plaintiff

400. At no time has either Defendant group disclosed the Insulin Pricing Scheme or the reasons for the false list prices produced by it.

The Manufacturer Defendants Deceived Plaintiff

401. At all times during the relevant period, the Manufacturer Defendants knew that the list prices, net prices, and payors' net costs (purchase prices) generated by the Insulin Pricing Scheme were false, excessive, and untethered to any legal, competitive, or fair market price.

402. The Manufacturer Defendants knew that these prices did not bear any rational relationship to the actual costs incurred or prices realized by Defendants, did not result from transparent or competitive market forces, and were artificially and arbitrarily inflated for the sole purpose of generating profits for Defendants.

403. The insulin market, and Defendants' business arrangement relating thereto, exhibit the key features of oligopolies (see Fig. 14)—concentration of numerous competitors into a small group of firms that dominates the market, high barriers to entry, ability to set and control prices, firm interdependence, and maximal revenues.

404. The Manufacturer Defendants also knew that payors, including Plaintiff, relied on the false list prices generated by the Insulin Pricing Scheme to pay for the at-issue drugs.

405. The Manufacturer and PBM Defendants further knew that Plaintiff—like any reasonable consumer, and particularly one with fiduciary obligations to its Beneficiaries—wanted and expected to pay a price reflecting the lowest fair market value for the drugs (which was not necessarily the same as the lowest price in the market, given that all prices were inflated due to the Insulin Pricing Scheme).

406. Despite this knowledge, the Manufacturer Defendants published the prices generated by the Insulin Pricing Scheme throughout the United States and Tennessee through

publishing compendia, in various promotional and marketing materials distributed by entities downstream in the drug supply chain, and directly to pharmacies which then used these prices to set the amount that the pharmacies charged for the at-issue drugs.

407. The Manufacturer Defendants also publish these prices to the PBMs and pharmacies, which then use them to charge diabetics and payors like Plaintiff for the at-issue drugs.

408. By publishing their prices throughout Tennessee, the Manufacturer Defendants held these prices out as a reasonable price upon which to base the prices that payors actually pay for the at-issue drugs.

409. These representations are false. The Manufacturer Defendants knew that their artificially inflated list prices were not remotely related to their cost, their fair market value in a competitive market, or the net price received for the at-issue drugs.

410. During the relevant period, the Manufacturer Defendants published prices in Tennessee at hundreds of dollars per dose for the same at-issue drugs that would have been profitable to Manufacturers at prices less than $10 per dose.

411. The Manufacturer Defendants also have publicly represented that they price the at-issue drugs according to each drug's value to the health care system and the need to fund innovation. For example, briefing materials prepared for Dave Ricks, Eli Lilly's CEO, as a panelist at the 2017 Forbes Healthcare Summit included "Reactive Key Messages" on pricing that emphasized the significant research and development costs for insulin. During the relevant period, executives from Sanofi and Novo Nordisk also falsely represented that research and development costs were key factors driving the at-issue price increases.[62]

[62] Drug Pricing Investigation, H.R. Comm. On Oversight and Reform, 117th Cong. (2021), https://web.archive.org/web/20211215170722/https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf (last visited Jan. 10, 2023).

412. To the contrary, between 2005 and 2018, Eli Lilly spent $680 million on R&D costs related to Humalog while earning $31.35 billion in net sales during that same time period. In other words, Eli Lilly made more than 46 times its reported R&D costs on Humalog during this portion of the relevant period, i.e., R&D costs amounted to about 2% of net sales (whereas R&D costs for pharmaceuticals typically amount to around 20% of total revenues). Novo Nordisk has spent triple the amount it spends on R&D on stock buyouts and shareholder dividend payouts in recent years.[63]

413. The January 2021 Senate Insulin Report found that the PBMs consider insulins to be "interchangeable" from "a clinical perspective" and that Manufacturers focus their R&D efforts on new insulin-related device, equipment, and other mechanical parts which are separate from insulin's formulation."[64]

414. A House Oversight Committee staff report concluded that "drug companies' claims that reducing U.S. prescription drug prices will harm innovation is overblown" and that "[m]any drug companies spent a significant portion of their R&D budget on finding ways to suppress generic and biosimilar competition while continuing to raise prices, rather than on innovative research."[65]

415. In sum, the Manufacturer Defendants affirmatively withheld the truth from Plaintiff and specifically made these misrepresentations in furtherance of the Insulin Pricing Scheme and

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[63] *Id.*

[64] Grassley & Wyden, *supra* note 2 at 5, 17.

[65] U.S. House of Reps., *Drug Pricing Investigation: Industry Spending on Buybacks, Dividends and Executive Compensation* (July 2021), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf (last visited Aug. 23, 2023).

to induce Plaintiff's reliance to purchase the at-issue drugs. The PBM Defendants Deceived Plaintiff

416. The PBM Defendants ensured that the Manufacturer Defendants' artificially inflated list prices harmed diabetics and payors by selecting the highest price at-issue drugs for preferred formulary placement and by requiring that their contracts with both pharmacies and with payors include such prices as the basis for payment.

417. The PBM Defendants perpetuate the use of the artificially inflated insulin prices because it allows them to obscure the actual price any entity in the drug pricing chain is paying for the at-issue drugs. This lack of transparency affords Defendants the opportunity to construct and perpetuate the Insulin Pricing Scheme and to profit therefrom at the expense of Tennessee payors, including Plaintiff.

418. At all times throughout the relevant period, the PBMs have purposefully, consistently, and routinely misrepresented that they negotiate with Manufacturer Defendants and construct formularies for the benefit of payors and patients by lowering the price of the at-issue drugs and by promoting the health of diabetics. Representative examples include: [66]

- Defendant CVS Caremark has for the past decade consistently stated in its annual reports that its design and administration of formularies are aimed at reducing the costs and improving the safety, effectiveness, and convenience of prescription drugs. CVS Caremark has further stated that it maintains an independent panel of doctors, pharmacists, and other medical experts to review and approve the selection of drugs based on safety and efficacy for inclusion on one of Caremark's template formularies and that CVS Caremark's formularies lower the cost of drugs.

- Likewise, Defendant Express Scripts has consistently represented that it works with clients, manufacturers, pharmacists, and physicians to increase efficiency in the drug distribution chain, to manage costs in the pharmacy benefit chain, and to improve members' health outcomes. Its annual reports consistently claim that in making formulary recommendations, Express Scripts' Pharmacy & Therapeutics Committee considers the drug's safety and efficacy, without any information on or

[66] CVS Health Annual Reports (Form 10-K) (FY 2010-2019); OptumRx Annual Reports (Form 10-K) (FY 2010-2019); Express Scripts Annual Reports (Form 10-K) (FY 2010-2019).

consideration of the cost of the drug, including any discount or rebate arrangement that Express Scripts negotiates with the Manufacturer, and that Express Scripts fully complies with the P&T Committee's clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of safety and efficacy.

- Similarly, Defendant OptumRx has consistently stated in its annual reports over the past decade that OptumRx's rebate contracting and formulary management assist customers in achieving a low-cost, high-quality pharmacy benefit. It has consistently claimed that it promotes lower costs by using formulary programs to produce better unit costs, encouraging patients to use drugs that offer improved value and that OptumRx's formularies are selected for health plans based on their safety, cost and effectiveness.

419. In addition to these general misrepresentations, the PBM Defendants have during the relevant period purposefully, consistently, and routinely made misrepresentations about the at-issue diabetes medications. Representative examples include:

- In a public statement issued in November 2010, CVS Caremark represented that it was focused on diabetes to "help us add value for our PBM clients and improve the health of plan members . . . a PBM client with 50,000 employees whose population has an average prevalence of diabetes could save approximately $3.3 million a year in medical expenditures."[67]

- In 2010, Andrew Sussman, Chief Medical Officer of CVS Caremark, stated on national television that "CVS is working to develop programs to hold down [diabetes] costs."[68]

- In a public statement issued in November 2012, CVS Caremark represented that formulary decisions related to insulin products "is one way the company helps manage costs for clients."[69]

- In 2016, Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts, said in an interview with a national publication that "[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors . . .

[67] Chain Drug Review, *CVS Expands Extracare for Diabetes Products* (May 11, 2010), https://www.chaindrugreview.com/cvs-expands-extracare-for-diabetes-products/ (last visited Jan. 15, 2023).

[68] CBS News, Diabetes Epidemic Growing (June 22, 2010, 11:29 AM), https://www.cbsnews.com/news/diabetes-epidemic-growing/ (last visited Aug. 23, 2023).

[69] Jon Kamp & Peter Loftus, *CVS' PBM Business Names Drugs It Plans to Block Next Year*, WSJ (Nov. 8, 2012), https://www.wsj.com/articles/SB10001424127887324439804578 107040729812454 (last visited Jan. 15, 2023).

[Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease."[70] Mr. Stettin also claimed that Express Scripts "broaden[s] insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs."[71]

- In a 2018 Healthline interview, Mark Merritt, longtime President of the PBM trade association PCMA, stated: "[Through their formulary construction], PBMs are putting pressure on drug companies to reduce insulin prices."[72]

- CVS Caremark's Chief Policy and External Affairs Officer claimed in the April 2019 hearings that CVS Caremark "has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers' price on behalf of employers, unions, government programs, and beneficiaries that we serve."[73]

- Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx, testified before the U.S. Congress in the April 2019 hearing that for "insulin products . . . we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers."[74]

- The PBM-funded trade association PCMA's website acknowledges, "the insulin market is consolidated, hindering competition and limiting alternatives, leading to higher list prices on new and existing brand insulins," but then misleadingly claims that "PBMs work hard to drive down costs using formulary management and rebates."[75]

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[70] https://www.bizjournals.com/stlouis/news/2016/08/31/express-scripts-launchesprogram-to-control.html (last visited Jan. 15, 2023).

[71] Angela Mueller, *Express Scripts Launches Program to Control Diabetes Costs*, St. Louis Bus. J. (Aug. 31, 2016), https://drugstorenews.com/pharmacy/express-scriptsimplements-latest-diabetes-care-value-program (last visited Jan. 15, 2023).

[72] Dave Muoio, *Insulin Prices: Are PBMs and Insurers Doing Their Part?*, Population Health Learning Network (Dec. 2016), https://www.hmpgloballearningnetwork.com/site/frmc/ article/insulin-prices-are-pbms-and-insurers-doing-their-part (last visited Jan. 15, 2023).

[73] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[74] *Id*.

[75] PCMA, *PCMA on National Diabetes Month: PBMs Lowering Insulin Costs, Providing Support to Patients* (Nov. 16, 2020), https://www.pcmanet.org/pcma-on-nationaldiabetes-month-pbms-lowering-insulin-costs-providing-support-to-patients/ (last visited Aug. 23, 2023); Visante, *Insulins: Managing Costs with Increasing Manufacturer Prices* (2020), https://www. pcmanet.org/ wpcontent/uploads/2020/08/PCMA_Visante-Insulins-Prices-and-Costs-.pdf.

420. The PBM Defendants not only falsely represent that they negotiate with the Manufacturer Defendants to lower the price of the at-issue diabetes medications for *payors*, but also for diabetic *patients* as well. Representative examples include:

- Express Scripts' code of conduct, effective beginning in 2015, states: "At Express Scripts we're dedicated to keeping our promises to *patients and clients* . . . This commitment defines our culture, and all our collective efforts are focused on our mission to make the use of prescription drugs safer and more affordable."[76] (emphasis added)

- Amy Bricker, former President of Express Scripts and PCMA board member, testified before Congress in April 2019: "At Express Scripts we negotiate lower drug prices with drug companies on behalf of our clients, *generating savings that are returned to patients* in the form of lower premiums and reduced out-of-pocket costs."[77] (emphasis added)

- Ms. Bricker of Express Scripts also testified that "Express Scripts remains committed to . . . *patients* with diabetes and creating affordable access to their medications."[78] (emphasis added)

- OptumRx CEO John Prince testified to the Senate: "We *reduce the costs of prescription drugs* [and] we are leading the way to ensure that *those discounts directly benefit consumers*. . . . OptumRx's pharmacy care services business is *achieving better health outcomes for patients, lowering costs* for the system, and *improving the healthcare experience for consumers*. . . . OptumRx negotiates better prices with drug manufacturers *for our customers and for consumers*.[79] (emphasis added)

- In its 2017 Drug Report, CVS Caremark stated that the goal of its pharmacy benefit plans is to ensure "that the cost of a drug is aligned with the value it delivers in terms of *patient* outcomes . . . in 2018, we are doing even more to help keep drugs affordable with our new Savings *Patients* Money initiative." (emphasis added)[80]

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[76] Express Scripts, *Code of Conduct*, https://www.expressscripts.com/aboutus/codeconduct/ExpressScriptsCodeOfConduct.pdf (last visited Jan. 10, 2023).

[77] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[78] *Id.*

[79] Grassley & Wyden, *supra* note 2—*Hearing Transcript* at 174, https://www.finance.senate.gov/imo/media/doc/435631.pdf (last visited Aug. 23, 2023).

[80] CVS Health, *2017 Drug Trend Report* (Apr. 5, 2018), https://payorsolutions.cvshealth.com/insights/2017-drug-trend-report (last visited Aug. 23, 2023).

- The PCMA website touts PBMs as "the only entity in the prescription drug supply and payment chain dedicated to reducing drug costs" and (contradicting the PBM representatives' Congressional testimony), that "when new manufacturers enter the market at a lower list price, PBMs use the competition to drive costs down."[81]

421. Not only have PBM Defendants intentionally misrepresented that they use their market power to save payors money, but they have specifically and falsely disavowed that their conduct drives prices higher. Representative examples include:

- On an Express Scripts' earnings call in February 2017, CEO Tim Wentworth stated: "Drugmakers set prices, and we exist to bring those prices down."[82]

- Larry Merlo, head of CVS Caremark sounded a similar refrain in February 2017: "Any suggestion that PBMs are causing prices to rise is simply erroneous."[83]

- In 2017, Express Scripts' Wentworth went on CBS News to argue that PBMs play no role in rising drug prices, stating that PBMs work to "negotiate with drug companies to get the prices down."[84]

- During the April 2019 Congressional hearings, when asked if PBM-negotiated rebates and discounts were causing the insulin price to increase, OptumRx's Chief Medical Officer Sumit Dutta answered: "we can't see a correlation when rebates raise list prices."[85]

- In 2019, when testifying under oath before Congress on the rising price of insulins, Amy Bricker—former President of Express Scripts and PCMA board member—testified: "I have no idea why the prices [for insulin] are so high none of it is the fault of rebates."[86]

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[81] PCMA, *PBMs Reduce Insulin Costs: PBMs are working to improve the lives of patients living with diabetes and their families*, https://www.pcmanet.org/insulin-managingcosts-with-increasing-manufacturer-prices/ (last visited Jan. 10, 2023).

[82] Samantha Liss, *Express Scripts CEO Addresses Drug Pricing 'Misinformation'*, St. Louis Post-Dispatch (Feb. 17, 2017), https://www.stltoday.com/business/local/expressscripts-ceo-addresses-drug-pricing-misinformation/article_8c65cf2a-96ef-5575-8b5c-95601ac51840.html (last visited Jan. 11, 2023).

[83] Lynn R. Webster, *Who Is To Blame For Skyrocketing Drug Prices?*, The Hill (July 27, 2017, 11:40 AM), https://thehill.com/blogs/pundits-blog/healthcare/344115-who-is-toblame-for-skyrocketing-drug-prices (last visited Jan. 11, 2023).

[84] CBS News, *Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices* (Feb 7, 2017), https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbmrising-drug-prices-mylan-epipen-heather-bresh/ (last visited Jan. 11, 2023).

[85] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[86] *Id.*

422. All of Defendants' public statements regarding insulin pricing have been consistent with the misrepresentations above and those detailed below. None have contradicted those misrepresentations or revealed the Insulin Pricing Scheme.

423. The PBM Defendants understand that payors like Plaintiff rely on the PBMs to achieve the lowest prices for the at-issue drugs and to construct formularies designed to improve access to medications. Plaintiff did so rely.

424. Throughout the relevant period, the PBM Defendants also falsely claimed they are transparent about the Manufacturer Payments and that the amounts they remit (or not) to payors. In fact, the PBM Defendants' disclosures of their ties to the Manufacturer Defendants were vague, equivocal, and misleading. Their manner of defining "rebates" in payor contracts was illusory and subject to indeterminate conditions and exceptions. The PBM Defendants thereby facilitated and obtained secret Manufacturer Payments far above and beyond the amount of "rebates" remitted to payors.

425. The PBMs' internal processes and accounting were and are abstruse and opaque, allowing them to overtly mislead the public and payors like Plaintiff.

426. In 2011, for example, OptumRx's President stated: "We want our clients to fully understand our pricing structure . . . [e]very day we strive to show our commitment to our clients, and one element of that commitment is to be open and honest about our pricing structure."[87]

[87] UnitedHealth Group, *Prescription Solutions by OptumRx Receives 4th Consecutive TIPPS Certification for Pharmacy Benefits Transparency Standards* (Sept. 13, 2011), https://web.archive.org/web/20210805182422/https://www.unitedhealthgroup.com/newsroom/2011/0913tipps.html (last visited Jan. 11, 2023). *See also, e.g.*, published version of press release at https://www.businesswire.com/news/home/20110913006224/en/Prescription-Solutions-by-OptumRx-Receives-4th-Consecutive-TIPPSSM-Certification-for-Pharmacy-Benefits-Transparency-Standards (last visited Aug. 23, 2023).

427. In a 2017 CBS News interview, Express Scripts' CEO represented, among other things, that Express Scripts was "absolutely transparent" about the Manufacturer Payments they receive and that payors "know exactly how the dollars flow" with respect to these Manufacturer Payments.[88]

428. When testifying before the Senate Finance Committee, CVS Executive Vice President Derica Rice stated: "[A]s it pertains to transparency overall, we at CVS Caremark are very supportive. We provide full visibility to our clients of all our contracts and the discounts that we negotiate on their behalf. . . . And transparency—today we report and fully disclose not only to our clients, but to CMS [Medicare]."[89]

429. At the same hearing, Steve Miller of Cigna (Express Scripts) testified: "we are a really strong proponent for transparency for those who pay for health care. So the patient should know exactly what they are going to pay. Our plan sponsors should know exactly what is in their contract."[90]

430. John Prince of OptumRx chimed in: "Senator, if our discounts were publicly available, it would hurt our ability to negotiate effectively. Our discounts are transparent to our clients."[91]

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[88] CBS News, *supra* note 79.

[89] Grassley & Wyden, *supra* note 2—*Hearing Transcript* at 28, 32, https://www.finance.senate.gov/imo/media/doc/ 435631.pdf (last visited Jan. 11, 2023).

[90] *Id.* at 32.

[91] *Id.*

431. When testifying before Congress in April 2019, Amy Bricker, then a Senior Vice President of Defendant Express Scripts, claimed transparency with payors and echoed Mr. Prince's need for confidentiality around discounts:[92]

> Ms. Bricker. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the government, health plans, what we negotiate for them is transparent to them. . . The reason I'm able to get the discounts that I can from the manufacturer is because it's confidential [to the public].
>
> ***
>
> Mr. Sarbanes. Yeah, because it's a secret. What about if we made it completely transparent? Who would be for that?
>
> ***
>
> Ms. Bricker. Absolutely not . . . [i]t will hurt the consumer. . . . prices will be held high.

432. As recently as May 2022, JC Scott—President of the PBM trade group PCMA—testified as follows before the Senate Commerce Committee:

> PBMs are proud of the work they do to reduce prescription drug costs, expand affordable access to medications, and improve patient outcomes. PBMs negotiate with drug companies to lower prescription drug costs PBMs advocate for patients in the fight to keep prescription drugs accessible and affordable.

433. Mirroring the PCMA website (¶¶ 429, 430, *supra*), Mr. Scott also testified, "The PBM industry is the only stakeholder in the chain dedicated to seeking lower costs."

434. During the relevant period—as seen above—PBM Defendants represented to Plaintiff that they constructed formularies and negotiated with the Manufacturer Defendants for the benefit of payors and patients to maximize drug cost savings while promoting the health of diabetics.

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[92] *Priced Out of a Lifesaving Drug, supra* note 35.

435. Throughout the relevant period, the PBMs made the foregoing and similar misrepresentations consistently and directly to Tennessee payors, including Cocke County, through bid proposals, member communications, invoices, formulary change notifications, and through extensive direct-to-consumer pull through efforts engaged in with the Manufacturers.

436. All of these representations are false. The Manufacturer and PBM Defendants in fact coordinated to publish the false prices and to construct the PBM formularies, causing the price of the at-issue drugs to skyrocket. For example:

a. In 2018, the US spent $28 billion (USD) on insulin compared with $484 million in Canada. The average American insulin user spent $3,490 on insulin in 2018 compared with $725 among Canadians.

b. Diabetics who receive their medications from federal programs that do not utilize PBMs also pay significantly less. For example, in December 2020, the United States House of Representatives Committee on Oversight and Reform issued a Drug Pricing Investigation Report finding that federal health care programs that negotiate directly with the Manufacturers (such as the Department of Veterans Affairs), and are thus outside the PBM Defendants' scheme, paid $16.7 billion less from 2011 through 2017 for the at-issue drugs than the Medicare Part D program, which relies on the PBM Defendants to set their at-issue drug prices (and are thus victims of the PBMs' concerted efforts to drive up the list prices).

437. Defendants knew their representations were false when they made them and coordinated to affirmatively withhold the truth from payors, including Plaintiff.

438. Defendants concealed the falsity of their representations by closely guarding their pricing negotiations, structures, agreements, sales figures, and the flow of money and other consideration between them.

439. The Defendants have never revealed the full amount of any drug-specific Manufacturer Payments exchanged between them.

440. The PBM Defendants do not disclose the terms of their agreements with the Manufacturers or the Manufacturer Payments they receive. Nor do they disclose the details related

to their agreements (formal or otherwise) with pharmacies. All of these revenue streams are beyond the scope of the payors' contractual audit rights.

441. Further, although PBMs negotiate drug-specific rebates with Manufacturers,[93] the PBM rebate payments to payor clients and summaries of such payments are in the aggregate, rather than on a drug-by-drug basis. It is impossible for payors like Plaintiff to tease out drug-specific rebates, much less the other undisclosed Manufacturer Payments. This allowed the PBM Defendants to hide the large Manufacturer Payments that they receive for the at-issue diabetes medications.

442. The PBM Defendants have gone so far as to sue governmental entities to block the release of details on their pricing agreements with the Manufacturers and pharmacies.

443. Even when audited by payors, the PBM Defendants routinely refuse to disclose their agreements with the Manufacturers and pharmacies, relying on overly broad confidential agreements, claims of trade secrets, and erecting other unnecessary roadblocks and restrictions.

444. Beneficiaries of the Plaintiff's health plans have no choice but to pay prices flowing from Defendants' inflated list prices because Beneficiaries need these medications to survive and the Manufacturer Defendants make virtually all diabetes medications available in the United States. The list prices generated by the Defendants' coordinated efforts directly impact out-of-pocket costs at the point of sale.

445. In sum, the entire insulin pricing structure created by the Defendants—from the false prices to the Manufacturers' misrepresentations related to the reason behind the price, to the inclusion of the false prices in payor contracts, to the non-transparent Manufacturer Payments, to

[93] Grassley & Wyden, *supra* note 2 at 40.

the misuse of formularies, to the PBMs' representations that they work to lower prices and promote the health of diabetics—is unconscionable, deceptive, and immensely lucrative.

446. Plaintiff did not know, because the Defendants affirmatively concealed, that (1) the Manufacturers and PBMs coordinated to create the PBM formularies in exchange for money and other consideration; (2) the list prices were falsely inflated; (3) the list prices were manipulated to satisfy PBM profit demands; (4) the list prices and net costs (purchase prices) paid by Plaintiff bore no relationship to the fair market value of the drugs themselves or the services rendered by the PBMs in coordinating their pricing; or (5) the entire insulin pricing structure Defendants created was false.

J. The Insulin Pricing Scheme Has Damaged Plaintiff

447. Plaintiff Cocke County provides health and pharmacy benefits to its Beneficiaries, including employees, retirees, and their dependents, who have numbered in the thousands throughout the relevant period.

448. One benefit Plaintiff provides the Beneficiaries of its healthcare plan is paying for their pharmaceutical needs.

449. Plaintiff entered into an agreement with CVS Caremark, whereby CVS Caremark agreed to provide Plaintiff prescription drug benefits and other at-issue services.

450. Plaintiff and Medco entered into an agreement whereby Medco agreed to provide Plaintiff prescription drug benefits and other at-issue services.

451. Express Scripts acquired Medco in 2012.

452. Plaintiff and OptumRx entered into an agreement whereby OptumRx agreed to provide Plaintiff prescription drug benefits and other at-issue services.

453. Plaintiff has renewed and had an active agreement in place with either Express Scripts, Medco, CVS Caremark, or Optum Rx.

454. Plaintiff requested proposals from the PBM Defendants for the at issue services.

455. In response to Plaintiff's requests, all PBM Defendants submitted proposals.

456. Plaintiff was unaware of the Insulin Pricing Scheme. Plaintiff relied on Defendants' public statements and material omissions.

457. Plaintiff contracted with Defendant Express Scripts, Inc., CVS Caremark, and OptumRx for PBM services.

458. Defendants' Insulin Pricing Scheme has cost Plaintiff an exorbitant amount of money in overcharges.

459. Indeed, since 2003 Cocke County has spent exorbitant amounts of money on the at-issue diabetes medications.

460. CVS Caremark's, Express Scripts', and OptumRx's respective relationships with Plaintiff were inherently unbalanced and their contracts adhesive. PBM Defendants had superior bargaining power and superior knowledge of their relationships with the Manufacturer Defendants, including those that ultimately dictate the drug costs Plaintiff incurred. Although PBM Defendants were supplying a vital service of a quasi-public nature, they exploited their superior positions to mislead Plaintiff and thwart its expectations, all at great expense to Cocke County.

461. The Defendants' misrepresentations, omissions, and misconduct—including and as manifested in the Insulin Pricing Scheme—directly and proximately caused economic damage to Plaintiff as a payor/purchaser of Defendants' at-issue diabetes medications.

462. A substantial proportion of the money Plaintiff spent on diabetes medications is attributable to Defendants' inflated prices, which did not arise from competitive market forces but, instead, exist solely by virtue of the Insulin Pricing Scheme.

463. Because of Defendants' success in concealing the Insulin Pricing Scheme through act and omission, no payor, including Plaintiff, knew (or should have known) during the relevant period that the prices for the at-issue diabetes medications were (and are) artificially inflated due to the Insulin Pricing Scheme.

464. As a result, despite receiving some rebates and incurring drug costs based on discounts off list prices, Plaintiff has unknowingly overpaid for the Manufacturer Defendants' diabetes medications, which would have cost far less but for the Insulin Pricing Scheme.

465. In short, the Insulin Pricing Scheme has directly and proximately caused Plaintiff to substantially overpay for diabetes medications.

466. Because Defendants continue to generate exorbitant, unfair, and deceptive prices for the at-issue drugs through the Insulin Pricing Scheme, the harm to Plaintiff is ongoing.

K. Defendants' Recent Efforts in Response to Rising Insulin Prices

467. In reaction to mounting political and public outcry, Defendants have taken action both on Capitol Hill and in the public relations space.

468. First, in response to public criticism, Defendants have increased their spending to spread their influence in Washington D.C.

469. For example, in recent years Novo Nordisk's political action committee ("PAC") has doubled its spending on federal campaign donations and lobbying efforts. In 2017 alone, Novo Nordisk spent $3.2 million lobbying Congress and federal agencies, its biggest ever investment in

directly influencing U.S. policymakers. Eli Lilly and Sanofi also have contributed millions of dollars through their PACs in recent years.

470. Second, Defendants have recently begun publicizing programs ostensibly aimed at lowering the cost of insulins.

471. These affordability measures fail to address the structural issues that caused the price hikes. Rather, these are public-relations measures that do not solve the problem.

472. For example, in March 2019, Defendant Eli Lilly announced that it would produce an authorized generic version of Humalog, "Insulin Lispro," and promised that it would "work quickly with supply chain partners to make [the authorized generic] available in pharmacies as quickly as possible."

473. However, in the months after Eli Lilly's announcement, reports raised questions about the availability of "Insulin Lispro" in local pharmacies.

474. Following this the staff of the Offices of U.S. Senators Elizabeth Warren and Richard Blumenthal prepared a report examining the availability of this drug. The investigative report, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, concluded that Eli Lilly's lower-priced, authorized generic insulin is widely unavailable in pharmacies across the country, and that the company has not taken meaningful steps to increase insulin accessibility and affordability.[94]

475. Eli Lilly did lower the price of Lispro by 40% effective January 1, 2022; but it is not included in any of the PBM Defendants' formularies as of January 2023.

[94] Sen. Elizabeth Warren & Sen. Richard Blumenthal, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, (Dec. 2019), https://www.warren.senate.gov/imo/media/doc/Inaccessible%20Insulin%20report.pdf (last visited Aug. 23, 2023).

476. In 2019, Novo Nordisk partnered with Walmart to offer ReliOn brand insulins for a discounted price at Walmart. However, experts have warned that the Walmart/Novo Nordisk insulins are not substitutes for most diabetics' regular insulins and should only be used in an emergency or when traveling. In particular, for many diabetics, especially Type 1 diabetics, these insulins can be dangerous. In any event, ReliOn is not included in any of the PBM Defendants' formularies as of January 2023.

477. Thus, Defendants' "lower priced" insulin campaigns have not addressed the problem, and the PBMs continue to exclude drugs with lower list prices despite their assurances of cost-savings for payors and Beneficiaries. Plaintiff continues to suffer harm caused by the Insulin Pricing Scheme.

478. Likewise, FDA in 2020 approved the biosimilar Insulin Glargine-yfgn (branded as Semglee), which is manufactured and sold by newcomers to the market—Viatris and Biocon Biologics.[95] Insulin Glargine-yfgn (Semglee) is interchangeable with Defendant Sanofi's Lantus product and, according Viatris, its list price is three times cheaper than Lantus. It is not included in any of the PBM Defendants' formularies as of January 2023.

[95] As explained in n.3, insulin now is regulated as a biologic rather than a drug. Biosimilars are analogous to generic drugs—approved versions of original products that are virtually identical to, and interchangeable with, the original product.

CLAIMS FOR RELIEF

First Cause of Action (Count I)
Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c)

(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx)

479. Plaintiff Cocke County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

480. Plaintiff brings this count against all Defendants for violations of 18 U.S.C. § 1962(c).

481. Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts and OptumRx are (a) culpable "persons" who (b) willfully and knowingly (c) committed and conspired to commit two or more acts of mail and wire fraud (d) through a "pattern" of racketeering activity that (e) involves an "association in fact" enterprise, (f) the results of which had an effect on interstate commerce.

A. Defendants Are Culpable "Persons" Under RICO

482. Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts, and OptumRx, separately, are "persons" as that term is defined in 18 U.S.C. § 1961(3) because each is capable of holding a legal or beneficial interest in property.

483. Each one of Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts, and OptumRx are separate entities and "persons" that are distinct from the RICO enterprises alleged below.

B. The Manufacturer-PBM RICO Enterprises

484. For the purposes of this claim, the RICO enterprises are six separate associations-in-fact consisting of one of each of the PBM Defendants and one of each of the Manufacturer

Defendants, including those entities' directors, employees, and agents: the Eli Lilly-CVS Caremark Enterprise; the Eli Lilly-OptumRx Enterprise; the Eli Lilly-Express Scripts Enterprise; the Novo Nordisk-CVS Caremark Enterprise; the Novo Nordisk-OptumRx Enterprise; the Novo Nordisk-Express Scripts Enterprise; the Sanofi-CVS Caremark Enterprise; the Sanofi-OptumRx Enterprise; and the Sanofi-Express Scripts Enterprise.

485. These association-in-fact enterprises are collectively referred to herein as the "Manufacturer-PBM Enterprises."

486. Each Manufacturer-PBM Enterprise is a separate, ongoing, and continuing business organization consisting of corporations and individuals associated for the common purpose of manufacturing, selling, and facilitating the purchase of the Manufacturer Defendants' products, including the at-issue drugs. For example:

a. The Eli Lilly-OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

b. The Eli Lilly-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

c. The Eli Lilly-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly

medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

d. The Novo Nordisk--OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

e. The Novo Nordisk-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

f. The Novo Nordisk-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

g. The Sanofi--OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications

including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

h. The Sanofi-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

i. The Sanofi-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

487. Each Manufacturer-PBM Enterprise engaged in the shared purpose of exchanging false list prices and secret Manufacturer Payments for preferred formulary positions for the at issue drugs in order to control the market for diabetes medications and profit off diabetics and payors, including Plaintiff.

488. The members of each enterprise are bound by contractual relationships, financial ties, and the ongoing coordination of activities.

489. There also is a common communication network by which Eli Lilly and OptumRx, Eli Lilly and Express Scripts, Eli Lilly and CVS Caremark, Novo Nordisk and OptumRx, Novo Nordisk and Express Scripts, Novo Nordisk and CVS Caremark, Sanofi and OptumRx, Sanofi and Express Scripts, and Sanofi and CVS Caremark share information and meet on a regular basis. These communications include, but are not limited to, communications relating to the use of false list prices for the at-issue diabetes medications and the regular flow of Manufacturer Payments from each Manufacturer Defendant to each PBM Defendant in exchange for formulary placement.

490. Each Manufacturer-PBM Enterprise functions as a continuing but separate unit separate and apart from the pattern of racketeering activity in which it engages. Each Manufacturer-PBM Enterprise, for example, engages in the manufacture, distribution and sale of medications and other products other than the at-issue insulin and insulin-analog medications. Additionally, each Manufacturer engages in conduct other than mail fraud and wire fraud in furtherance of the Insulin Pricing Scheme.

491. At all relevant times, each of the Manufacturer-PBM Enterprises was operated and conducted for unlawful purposes by each Manufacturer Defendant and PBM Defendant, namely, carrying out the Insulin Pricing Scheme.

492. Each Manufacturer-PBM Enterprise derived secret profits from these activities that were greater than those any one of the Manufacturer Defendants or PBM Defendants could obtain absent their misrepresentations regarding their pricing schemes.

493. To accomplish this common purpose, each Manufacturer Defendant periodically and systematically inflated the prices of the at-issue drugs and then secretly paid a significant, yet undisclosed, portion of this inflated price back to the PBM Defendants in the form of Manufacturer Payments.

494. Each Manufacturer-PBM Enterprise did so willfully and with knowledge that Plaintiff paid for the at-issue drugs at prices directly based on the false list prices.

495. Each Manufacturer-PBM Enterprise's inflation of the list prices and secret Manufacturer Payments was a quid pro quo exchange for preferred formulary placement.

496. Each Manufacturer-PBM Enterprise concealed from Plaintiff that these false prices and secret Manufacturer Payments resulted in each Manufacturer gaining formulary access without requiring significant price reductions and resulted in higher profits for each PBM Defendant,

whose earnings increase the more inflated the price is and the more payment it receives from each Manufacturer Defendant.

497. Each Manufacturer-PBM Enterprise also shares a common purpose of perpetuating the use of the false list prices for the at-issue drugs as the basis for the price that payors, including Plaintiff, and diabetics pay for diabetes medications.

498. The Manufacturer Defendants would not be able to offer large pricing spreads to the PBM Defendants in exchange for favorable formulary positions without the use of the false list prices as the basis for the price paid by diabetics and payors, including Plaintiff, for the at-issue drugs.

499. The PBM Defendants share this common purpose because nearly all the revenue and profit generated from the at-issue drugs is tied to the false inflated prices generated by the Insulin Pricing Scheme. Without diabetics and payors, including Plaintiff, paying for diabetes medications based on the inflated list prices, their profits from the Insulin Pricing Scheme would decrease.

500. As a result, the PBM Defendants have, with the knowing and willful participation and assistance of each Manufacturer Defendant, engaged in hidden profit-making schemes falling into four general categories: (a) garnering undisclosed Manufacturer Payments from each Manufacturer Defendant that the PBM Defendants retain to a large extent; (b) generating substantial profits from pharmacies because of the falsely inflated prices; (c) generating profits on the diabetes medications sold through the PBM Defendants' own mail-order and retail pharmacies; and (d) keeping secret discounts each Manufacturer Defendant provides in association with the PBM Defendants' mail-order and retail operations.

501. At all relevant times, each PBM Defendant and each Manufacturer Defendant have been aware of their respective Manufacturer-PBM Enterprise's conduct, have been knowing and willing participants in and coordinator of that conduct and have reaped profits from that conduct.

502. None of the PBM Defendants or the Manufacturer Defendants alone could have accomplished the purposes of the Manufacturer-PBM Enterprises without the other entities.

C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme

503. Each Manufacturer-PBM Enterprise knowingly made material misrepresentations to the public and Plaintiff in furtherance of the Insulin Pricing Scheme, including publishing artificially inflated prices for insulin on published indices and representing that:

a. the false list prices for the at-issue diabetes medications were reasonably related to the actual prices realized by Defendants and were a reasonable and fair basis on which to base the price Plaintiff paid for these drugs;

b. each Manufacturer priced its at-issue drugs according to each drug's value to the healthcare system and the need to fund innovation;

c. the Manufacturer Payments paid back to each PBM Defendant for each at-issue drug were for Plaintiff' benefit;

d. all "rebates and discounts negotiated by the PBM Defendants with the Manufacturer Defendants were remitted to Plaintiff;

e. the "rebates" negotiated by the members of each enterprise saved Plaintiff money;

f. each Manufacturer Defendant and each PBM Defendant were transparent with Plaintiff regarding the Manufacturer Payments and the PBMs did not retain any funds associated prescription drug rebates or the margin between guaranteed reimbursement rates and the actual amount paid to the pharmacies; and

g. the PBM Defendants constructed formularies in a manner that lowered the price of the at-issue drugs and promoted the health and safety of diabetics.

504. Each false list price published by the Manufacturer Defendants constituted a material misrepresentation to Plaintiff and the public, in that each purported to be a fair market price for an at-issue drug, and each omitted to disclose the fraudulent spread between the list price and the net price of the medication or the basis therefor. Examples of other affirmative representations by each RICO Defendant in furtherance of each enterprise's Insulin Pricing scheme are alleged herein.

505. At all times relevant to this Complaint, each Manufacturer-PBM Enterprise knew the above-described representations to be false.

506. At all times relevant to this Complaint, each Manufacturer-PBM Enterprise intentionally made these representations for the purpose of inducing Plaintiff into paying artificially inflated prices for diabetes medications.

507. Plaintiff relied on the material misrepresentations and omissions made by each Manufacturer-PBM Enterprise in paying prices for the at-issue diabetes medications based upon the false prices generated by Insulin Pricing Scheme.

508. Additionally, each PBM-Manufacturer Enterprise relied on the list prices negotiated and published by the other PBM-Manufacturer enterprises in setting their own list prices and determining the value of the kickbacks paid to the PBMs. Plaintiff were injured by the inflated prices that arose as a result.

509. PBM Defendants convinced Plaintiff to pay prices for the at-issue drugs based on the false list price by utilizing the misrepresentations listed above to convince Plaintiff that they

had secured lower prices when, in fact, they did the opposite, all while concealing the Insulin Pricing Scheme.

510. Without these misrepresentations and each RICO Defendant's failure to disclose the Insulin Pricing Scheme, each Manufacturer-PBM Enterprise could not have achieved its common purpose, as Plaintiff would not have been willing to pay these false list prices.

D. Defendants' Use of the U.S. Mails and Interstate Wire Facilities

511. Each of the Manufacturer-PBM Enterprises engaged in and affected interstate commerce because each engaged in the following activities across state boundaries: the sale, purchase and/or administration of diabetes medications; the setting and publishing of the prices of these drugs; and/or the transmission of pricing information of diabetes medications; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission of diabetes medications through mail-order and retail pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of diabetes medications; and/or the negotiations and transmissions of contracts related to the pricing of and payment for diabetes medications.

512. Each Manufacturer-PBM Enterprise participated in the administration of diabetes medications to millions of individuals located in all 50 states, including in this District.

513. Each Manufacturer Defendant's and each PBM Defendant's illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

514. The nature and pervasiveness of the Insulin Pricing Scheme, which included each Manufacturer Defendant's and each PBM Defendant's corporate headquarters operations,

necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other and with pharmacies, physicians, payors, and diabetics throughout the United States.

515. Each Manufacturer-PBM Enterprise's use of the U.S. mails and interstate wire facilities to perpetrate the Insulin Pricing Scheme involved thousands of communications including:

a. marketing materials about the published prices for diabetes medications, which each Manufacturer Defendant sent to each PBM Defendant across the country, in Cocke County, and throughout Tennessee;

b. written and oral representations of the false list prices of diabetes medications that each Manufacturer Defendant and each PBM Defendant made at least annually and, in many cases, several times during a single year to the public;

c. thousands of written and oral communications discussing, negotiating, and confirming the placement of each Manufacturer Defendant's diabetes medications on each PBM Defendant's formularies;

d. written and oral representations made by each Manufacturer Defendant regarding information or incentives paid back to each PBM Defendant for each diabetes medications sold and/or to conceal these incentives or the Insulin Pricing Scheme;

e. written communications made by each Manufacturer Defendant, including checks, relating to Manufacturer Payments paid to each PBM Defendant to persuade them to advocate the at-issue diabetes medications;

f. written and oral communications with U.S. government agencies that misrepresented what the published prices were or that were intended to deter investigations into the

true nature of the published prices or to forestall changes to reimbursement based on something other than published prices;

g. written and oral communications with payors, including Plaintiff, regarding the price of diabetes medications;

h. written and oral communications to Plaintiff, including marketing and solicitation material sent by each PBM Defendant regarding the existence, amount, or purpose of payments made by each Manufacturer Defendant to each PBM Defendant for the diabetes medications described herein and the purpose of each PBM Defendants formularies;

i. transmission of published prices to third parties and payors, including Plaintiff; and

j. receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities-the wrongful proceeds of the Insulin Pricing Scheme.

516. Although Plaintiff plead the dates of certain communications in allegations incorporated into this Count, it cannot allege the precise dates of others without access to books and records within each RICO Defendant's exclusive custody and control. Indeed, an essential part of the successful operation of the Insulin Pricing Scheme depended upon secrecy, and each Manufacturer Defendant and PBM Defendant took deliberate steps to conceal its wrongdoing.

E. Conduct of the Manufacturer-PBM Enterprises' Affairs

517. Each Manufacturer Defendant and PBM Defendant participates in the operation and management of Manufacturer-PBM Enterprises with which it is associated and, in violation of Section 1962(c) of RICO, and conducts or participates in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation is carried out in the following ways:

a. Each Manufacturer Defendant directly controls the secret Manufacturer Payments it provides to each PBM Defendant for its diabetes medications.

b. The PBM Defendants directly manage and control their respective drug formularies and the placement of the at-issue diabetes medications on those formularies.

c. The PBM Defendants intentionally select higher-priced diabetes medications for formulary placement and exclude lower priced ones in order to generate larger profits and they coordinate with the Manufacturer Defendants to increase the availability and use of higher-priced medications because they are more profitable for both groups of Defendants.

d. Each Manufacturer Defendant directly controls the publication of the false list prices generated by the Insulin Pricing Scheme.

e. Each Manufacturer Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform each PBM Defendant of the profit potential from its diabetes medications.

f. Each PBM Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform payors and the public of the benefits and cost-saving potential of each PBM Defendant's formularies and negotiations with the Manufacturers.

g. Each PBM Defendant directs and controls each enterprise's direct relationships with payors such as Plaintiff by negotiating the terms of and executing the contracts that govern those relationships.

h. Each PBM Defendant directs and controls each enterprise's Insulin Pricing Scheme by hiding, obfuscating, and laundering Manufacturer Payments through their affiliated

entities in order to retain a large and undisclosed proportion of the Manufacturer Payments to the detriment of payors, including Plaintiff.

i. Each PBM Defendant distributes through the U.S. mail and interstate wire facilities, promotional and other materials that claim the Manufacturer Payments paid from each Manufacturer Defendant to each PBM Defendant save Plaintiff and other payors money on the at-issue drugs.

j. Each Manufacturer Defendant represented to Plaintiff-by publishing and promoting false list prices without stating that these published prices differed substantially from the prices realized by each Manufacturer Defendant and each PBM Defendant-that the published prices of diabetes medications reflected or approximated the actual price realized by Defendants and resulted from transparent and competitive, fair market forces.

F. Defendants' Pattern of Racketeering Activity

518. Each Manufacturer Defendant and each PBM Defendant have conducted and participated in the affairs of their respective Manufacturer-PBM Enterprises through a pattern of racketeering activity, including acts that are unlawful under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud.

519. Each Manufacturer Defendant's and each PBM Defendant's pattern of racketeering involved thousands, if not hundreds of thousands of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of the Insulin Pricing Scheme. Each of these mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the

meaning of 18 U.S.C. § 1961 (5), in which each Manufacturer Defendant and each PBM Defendant intended to defraud Plaintiff.

520. By intentionally and falsely inflating the list prices, by misrepresenting the purpose behind both the Manufacturer Payments made from each Manufacturer Defendant to each PBM Defendant and each PBM Defendant's formulary construction, and by subsequently failing to disclose such practices to Plaintiff, each Manufacturer Defendant and each PBM Defendant engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

521. Each Manufacturer Defendant's and each PBM Defendant's racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiff.

522. Each separate use of the U.S. mails and/or interstate wire facilities employed by each Manufacturer Defendant and each PBM Defendant was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff.

523. Each Manufacturer Defendant and each PBM Defendant engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Manufacturer-PBM Enterprises with which each of them is and was associated in fact.

G. The RICO Defendants' Motive

524. Each Manufacturer Defendant's and each PBM Defendant's motive in creating and operating the Insulin Pricing Scheme and conducting the affairs of the Manufacturer-PBM Enterprises described herein was to control the market for diabetes medications and falsely obtain sales of and profits from diabetes medications.

525. The Insulin Pricing Scheme was designed to, and did, encourage others, including payors like Plaintiff, to advocate the use of each Manufacturer Defendant's products and to pay for those diabetes medications based on a falsely inflated price. Each Manufacturer Defendant used the Insulin Pricing Scheme to obtain formulary placement to sell more of its drugs without having to cut into its profits. Each PBM Defendant used the Insulin Pricing Scheme to falsely inflate the price payors like Plaintiff paid for diabetes medications in order to profit off the Insulin Pricing Scheme, as discussed above.

H. The Manufacturer-PBM Enterprises' Insulin Pricing Scheme Injured Plaintiff

526. Each Manufacturer-PBM Enterprise's violations of federal law and pattern of racketeering activity have directly and proximately caused Plaintiff to be injured in their business or property.

527. The prices Plaintiff pay for the at-issue drugs are tied directly to the false list prices generated by the Insulin Pricing Scheme.

528. No other intermediary in the supply chain has control over or is responsible for the list prices on which nearly all Plaintiff' payments are based other than the Manufacturer-PBM Defendant Enterprises.

529. Defendants collectively set the prices that Plaintiff paid for the at-issue diabetes medications.

530. During the relevant period, Express Scripts, CVS Caremark, and OptumRx provided PBM services to Plaintiff and benefited therefrom.

531. During the relevant period, Plaintiff paid Express Scripts, CVS Caremark, and OptumRx for the at issue drugs.

532. Each Manufacturer-PBM Enterprise controlled and participated in the Insulin Pricing Scheme that was directly responsible for the false list prices upon which the price Plaintiff paid was based.

533. Thus, Plaintiff was damaged by reason of the Insulin Pricing Scheme. But for the misrepresentations and false prices created by the Insulin Pricing Scheme that each Manufacturer-PBM Enterprise employed, Plaintiff would have paid less for diabetes medications.

534. While Defendants' scheme injured an enormous number of payors and plan members, Plaintiff's damages are separate and distinct from those of any other victim that was harmed by the Manufacturer-PBM Defendant Enterprises' Insulin Pricing Scheme.

535. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Plaintiff for three times the damages that were sustained, plus the costs of bringing this action, including reasonable attorneys' fees.

536. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(a) of RICO, Plaintiff seeks injunctive relief against each Manufacturer Defendant and each PBM Defendant for their fraudulent reporting of their prices and their continuing acts to affirmatively misrepresent and/ or conceal and suppress material facts concerning their false and inflated prices for diabetes medications, plus the costs of bringing this suit, including reasonable attorneys' fees.

537. Absent an injunction the effects of this fraudulent, unfair, and unconscionable conduct will continue. Plaintiff continues to purchase the at-issue diabetes medications. Plaintiff will continue to pay based on the Defendants' false list prices. This continuing fraudulent, unfair, and unconscionable conduct is a serious matter that calls for injunctive relief as a remedy. Plaintiff

seeks injunctive relief, including an injunction against each Manufacturer and each PBM Defendant, to prevent them from affirmatively misrepresenting and/or concealing and suppressing material facts concerning their conduct in furtherance of the Insulin Pricing Scheme.

Second Cause of Action (Count II)
Violations of RICO, 18 U.S.C. § 1962(d)
By Conspiring to Violate 18 U.S.C. § 1962(c)
(against all Defendants)

538. Plaintiff re-alleges and incorporates herein by reference the allegations set forth in the preceding paragraphs.

539. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

540. Defendants have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in the Insulin Pricing Scheme.

541. As set forth in detail above, Defendants each knowingly agreed to facilitate the Insulin Pricing Scheme and each has engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy. Specifically, Defendants agreed to and did inflate the prices of the at-issue drugs in lockstep to achieve an unlawful purpose; Defendants agreed to and did make false or misleading statements or material omissions regarding the reasons for these price increases, the purpose of the Manufacturer Payments exchanged between Defendants and the PBMs' formulary construction; and PBMs agreed to and did, in concert, request and receive larger Manufacturer Payments and higher prices in exchange for formulary placement.

542. The nature of the above-described Defendant co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that

they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

543. Defendants have engaged and continue to engage in the commission of overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail fraud in violations of 18 U.S.C. § 1341;

b. Multiple instances of wire fraud in violations of 18 U.S.C. § 1343; and

c. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

544. Defendants' conspiracy to violate the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff has been injured in its property by reason of these violations: Plaintiff has paid more for the at-issue drugs than it would have but for Defendants' conspiracy to violate 18 U.S.C. § 1962(c).

545. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Plaintiff for three times the damages this District has sustained, plus the cost of this suit, including reasonable attorneys' fees.

Third Cause of Action (Count III)
Unlawful Restraint of Trade
Tenn. Code Ann. §§ 47-25-101, *et seq*.
(against all Defendants)

546. Plaintiff Cocke County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

547. As detailed in the foregoing paragraphs, Defendants entered into, established, and maintained a continuing contract, agreement, arrangement, or combination in unreasonable restraint of trade.

548. The purpose and effect of the arrangement was to effect the Insulin Pricing Scheme.

549. The contract, agreement, arrangement, or combination had a direct, substantial, and reasonably foreseeable effect upon commerce within the United States and within Tennessee by: (a) increasing prices paid by Plaintiff for the at-issue diabetes medications; (b) depriving Plaintiff of savings that they would otherwise have received in the absence of the conspiracy; and (c) depriving Plaintiff of free, open, and unrestricted competition in the purchase of the at-issue drugs sold by Defendants.

550. As a result of Defendants' unlawful conduct, Plaintiff has been injured by paying inflated prices for the at-issue diabetes medications.

551. By engaging in the conduct described above, Defendants formed a contract, agreement, arrangement, or combination in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*

Fourth Cause of Action (Count IV)
Violation of Tennessee Consumer Protection Act
Tenn. Code Ann. §§ 47-18-101, *et seq*.
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx)

552. Plaintiff Cocke County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

553. The Tennessee Consumer Protection Act of 1977 makes unlawful "[u]nfair or deceptive acts or practices affecting the conduct of any trade or commerce[.]."[96]

554. Plaintiff is a "person" within the meaning of Tenn. Code Ann. § 47-18-103(18).

555. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx are each a "person" within the meaning of Tenn. Code Ann. § 47-18-103(18).

[96] Tenn. Code Ann. § 47-18-104(a).

556. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark's conduct, collectively and as individuals, as described in this Complaint, constitutes deceptive acts in violation of the Tennessee Consumer Protection Act.

557. Because these Defendants' willful and knowing conduct caused injury to Plaintiff, Plaintiff seeks to recover actual damages; discretionary treble damages; punitive damages; reasonable attorneys' fees and costs; an order enjoining Defendants' unlawful conduct; and any other just and proper relief available under.

558. By engaging in the Insulin Pricing Scheme, as described herein, Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx have committed acts of unfair and deceptive trade practices in the conduct of trade or commerce within Tennessee and Cocke County causing harm to Plaintiff as a reimbursor for, and purchaser and payor of, the at-issue drugs.

559. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx have engaged in the following materially misleading conduct, which constitutes deceptive trade practice in violations of the Tennessee Consumer Protection Act:

- Making false and misleading misrepresentations of fact that the prices for the at-issue diabetes medications were legal, competitive, and fair market value prices. In particular:
    - A characteristic of every commodity in Tennessee's economy is its price, which is represented by every seller to every buyer that the product being sold is being sold at a legal, competitive, and fair market value.
    - At no point did these Defendants reveal that the prices associated with the lifesaving diabetic treatments at issue herein were not legal, competitive, or at fair market value.
    - At no point did these Defendants disclose that the prices associated with the at-issue drugs were generated by the Insulin Pricing Scheme.

- At least once per year for each year during the relevant period, these Defendants reported and published false prices for each at-issue drug and in doing so represented that the reported prices were the actual, legal and fair prices for these drugs and resulted from competitive market forces.

- In addition, by granting the at-issue drugs preferred formulary position—formulary positions that the PBMs represent are reserved for reasonably priced drugs and that are meant to promote the health of diabetics—the PBM Defendants knowingly and purposefully utilized the false prices that were generated by the Insulin Pricing Scheme.

- By granting the at-issue diabetes medications preferred formulary positions, the PBM Defendants ensured that prices generated by the Insulin Pricing Scheme would harm Plaintiff.

- The PBM Defendants also misrepresented their formularies promoted the cost-savings to Plaintiff.

- Defendants' representations are false, and Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark knew they were false. Defendants knew that the prices they reported and utilized are artificially inflated for the purpose of maximizing profits through the Insulin Pricing Scheme.

- These Defendants also knew that the PBMs' formulary construction fueled the precipitous price increases that damaged Plaintiff's financial well-being.

- Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark affirmatively withheld this truth from Plaintiff Cocke County, even though these Defendants knew that the Plaintiff's intention was to pay the lowest possible price for diabetes medications and expectation was to pay a legal, competitive price that resulted from transparent market forces.

- Making false and misleading misrepresentations of fact related to the Manufacturer Payments and the negotiations that occurred between the PBM and Manufacturer Defendants.

- The PBM Defendants knowingly made false and misleading statements concerning the reasons for, existence of, and amount of price reductions by misrepresenting that the Manufacturer Payments lower the overall price of diabetes medications and promote the health of diabetics.

- These representations were false, and Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark knew they were false. The PBM Defendants knew that the Manufacturer Payments were not reducing the overall price of diabetes medications but rather are an integral part of the Insulin Pricing Scheme and are responsible for the inflated prices.

560. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx continue to make these misrepresentations and publish prices generated by the Insulin Pricing scheme, and Plaintiff continues to purchase diabetes medications at inflated prices.

561. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx acted knowingly and in a willful, wanton or reckless disregard for the safety of others in committing the violation of the Tennessee Consumer Protection Act described herein.

562. Each at-issue purchase Plaintiff made for diabetes medications at the prices generated by the Insulin Pricing Scheme constitutes a separate violation of the Tennessee Consumer Protection Act.

563. The acts and practices alleged herein are ongoing, repeated, and affect the public interest.

564. The acts and practices alleged herein substantially impact the community of diabetics, their families, healthcare providers, and the public, and have caused substantial actual harm, including to Plaintiff and its beneficiaries.

565. These Defendants' acts and practices in violation of the Tennessee Consumer Protection Act caused Plaintiff to suffer injuries alleged herein, including but not limited to paying excessive and inflated prices for diabetes medications as described herein.

566. As a direct and proximate result of these Defendants' conduct in committing the above and foregoing violations of the Tennessee Consumer Protection Act, these Defendants are directly and jointly and severally liable to Plaintiff for all restitution, damages, punitive damages, treble damages, penalties and disgorgement for which recovery is sought herein, including but not limited to the Plaintiff paying excessive and inflated prices for diabetes medications described herein every time it paid for an at-issue drug.

567. Additionally, Plaintiff did not receive the benefit of its bargain, or otherwise paid a price premium, for the at-issue diabetes medications because it paid an artificially inflated price due to these Defendants' illegal practices.

Fifth Cause of Action (Count V)
Breach of Contract
(against Defendants Express Scripts, CVS Caremark, and OptumRx)

568. Plaintiff Cocke County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

569. In Tennessee, all contracts—including those between the PBM Defendants and Plaintiff—imply a covenant of good faith and fair dealing in the course of performance (the "Covenant").[97]

570. The Covenant protects "the parties' reasonable expectations as well as their right to receive the benefits of their agreement"[98] and is breached when "a party to the contract exercises discretion authorized in a contract in an unreasonable way."[99]

571. By engaging in the conduct alleged in this Complaint, specifically by arranging with Insulin Manufacturers to hide portions of their rebates by, *inter alia*, relabeling a portion of the rebates as "administrative fees" such that they do not have to be "passed through" to Plaintiff, the PBM Defendants deprived Plaintiff of its rights to receive the benefits of their agreement.

572. PBM Defendants made such arrangements willfully, with the dishonest purpose of enriching themselves at the expense of payors such as Plaintiff. Furthermore, they took efforts to

[97] *See, e.g.*, *Wallace v. Nat'l Bank of Commerce*, 938 S.W.2d 684, 686 (Tenn. 1996).

[98] *Dick Broad. Co. v. Oak Ridge FM, Inc.*, 395 S.W.3d 653, 666 (Tenn. 2013).

[99] *Universal Props. v. Regions Bank*, No. 3:11-cv-538, 2012 U.S. Dist. LEXIS 135256, at *23 (E.D. Tenn. Sep. 21, 2012)).

conceal the terms of these arrangements so that payors such as Plaintiff could not discover that they were not receiving the fruits of their contract.

573. As a direct and proximate result of PBM Defendants' breach of the covenant of good faith and fair dealing, Plaintiff did not receive the benefit of its bargain and paid a price-premium for the at-issue diabetes medications because it paid an artificially inflated price due to these Defendants' illegal practices.

Sixth Cause of Action (Count VI)
Unjust Enrichment
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx)

574. Plaintiff Cocke County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

575. This cause of action is alleged in the alternative to any claim Plaintiff may have for legal relief.

576. Plaintiff conferred a benefit upon Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx. These Defendants deceived Plaintiff Cocke County and have received a financial windfall from the Insulin Pricing Scheme at Plaintiff's expense.

577. These Defendants wrongfully secured and retained unjust benefits from Plaintiff in the form of amounts paid for diabetes medications and fees and payments collected based on the prices generated by the Insulin Pricing Scheme. They did not adequately compensate Plaintiff therefor.

578. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx were aware of the benefit, voluntarily accepted it, and retained and appreciated the benefit, to which it was not entitled, at Plaintiff's expense.

579. It is inequitable and unfair for these Defendants to retain these benefits.

580. The benefit these Defendants have wrongfully retained is in an amount not less than the difference between the reasonable or fair market value of the at-issue drugs for which Plaintiff paid and the actual value of the at-issue drugs these Defendants delivered.

581. Accordingly, Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx should not be permitted to retain the proceeds from the benefits conferred upon them by Plaintiff, which seeks disgorgement of these Defendants' unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and seeks restitution and/or recission, in an equitable and efficient fashion to be determined by the Court.

582. As a direct and proximate cause of these Defendants' unjust enrichment at the expense of Plaintiff as referenced above, Plaintiff has suffered and continues to suffer ascertainable losses and damages as specified herein in an amount to be determined at trial.

MOTION FOR INJUNCTION

583. Plaintiff Cocke County re-alleges and incorporates the preceding paragraphs.

584. By Defendants' violations of the Tennessee Consumer Protection Act, RICO, and common law, Plaintiff has suffered, and will continue to suffer, immediate and irreparable injury, loss, and damage, as discussed herein.

585. The ongoing and threatened injury to Plaintiff and its beneficiaries outweighs the harm that an injunction might cause Defendants.

586. As a direct and proximate result of the conduct of the Defendants in committing the above and foregoing acts, Plaintiff moves the Court for injunctive relief against the Defendants pursuant Tenn. Code Ann. § 47-18-109(b) and 18 U.S.C. § 1964(a), thereby enjoining Defendants from committing future violations of the Tennessee Consumer Protection Act and RICO.

587. Granting an injunction is consistent with the public interest because it will protect the health and economic interests of Plaintiff, as well as the integrity of the Tennessee marketplace.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff Cocke County prays for entry of judgment against the Defendants for all the relief requested herein and to which the Plaintiff may otherwise be entitled, specifically, but without limitation, to-wit:

A. That the Court determine that Defendants have violated the Tennessee Consumer Protection Act, have violated RICO, have breached their contract with Defendants, and have been unjustly enriched;

B. Judgment in favor of Plaintiff and against the Defendants for damages in excess of the minimum jurisdictional requirements of this Honorable Court, in a specific amount to be proven at trial;

C. That Plaintiff be granted the following specific relief:

1. In accordance with Tenn. Code Ann. § 47-18-109(b) and 18 U.S.C. § 1964(a), that Defendants, their affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be enjoined and restrained from in any manner continuing, maintaining or renewing the conduct, contract, conspiracy or combination alleged herein in violation of the and RICO, or from entering into any other contract, conspiracy or combination having a similar purpose or effect, and from adopting or following any practice, plan, program or device having a similar purpose or effect;

2. That Plaintiff:

i. be awarded restitution, damages, disgorgement, penalties and/or all other legal and equitable monetary remedies available under the state laws set forth in this Complaint and the general equitable powers of this Court in an amount according to proof;

ii. be awarded punitive damages because Defendants knowingly, willfully, wantonly and intentionally harmed the health, wellbeing and financial interests Plaintiff and its Beneficiaries;

iii. be awarded pre- and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the initial complaint in this action;

iv. recover its costs of suit, including its reasonable attorney's fees, as provided by law and pursuant to the Tennessee Consumer Protection Act and 18 U.S.C. § 1964(c); and

v. be awarded such other, further and different relief as the case may require and the Court may deem just and proper under the circumstances.

JURY DEMAND

Plaintiff Cocke County demands trial by jury on all issues so triable.

Dated: June 12, 2024

/s/ Michael J. Fuller, Jr.

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